Arms	Assigned Interventions
1 This is a double masked, prospective, randomized study in which five groups of approximately 30 patients meeting the eligibility criteria will be randomly assigned in a balanced ratio to receive a series of ITV injections of VEGF Trap into the study eye at 4- or 12-week intervals over a 12-week period. Beginning with Week 16, all patients will be evaluated every 4 weeks for continued dosing for up to one year. The fellow eye may also be eligible for treatment with VEGF Trap beginning at this	Drug: VEGF Trap Subjects in Group A will receive 2 ITV injections of 0.5 mg VEGF Trap at 12-week intervals; Group B subjects will receive 4 ITV injections of 0.5 mg VEGF Trap at 4-week intervals; Group C subjects will receive 2 injections of 2.0 mg VEGF Trap at 12-week intervals; Group D subjects will receive 4 injections of 2.0 mg VEGF Trap at 4-week intervals, and Group E subjects will receive 2 injections of 4.0 mg VEGF Trap at 12-week intervals. Other Names: • Aflibercept

Outcome Measures

Primary Outcome Measures:

1. Safety, biological effect (optical coherence tomography [OCT], fluorescein angiography, visual acuity)
   From baseline to week 12

Secondary Outcome Measures:

2. Pharmacokinetics, immunogenicity, quality of life
   From baseline to week 12

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subfoveal CNV secondary to AMD.
- Central retinal (including lesion) thickness ≥ 300 µm as measured by OCT.
- Early Treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity of 73 letters to 34 letters.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Day 1.
- Aphakia.
- Significant subfoveal atrophy or scarring.
- Prior treatment with the following in the study eye:
  - Subfoveal thermal laser therapy.
  - Submacular surgery or other surgical intervention for the treatment of AMD.
  - Extrafoveal laser coagulation treatment within 12 weeks prior to Day 1.
  - Photodynamic therapy (PDT) within 12 weeks prior to Visit 2 (Day 1).
  - Pegaptanib sodium (Macugen) within 8 weeks of Visit 2 (Day 1).
  - Juxtascleral steroids or anecortave acetate within 24 weeks (6 months) prior to Visit 2 (Day 1).
  - Intravitreal administration of triamcinolone acetonide or other steroids within 24 weeks prior to Visit 2 (Day 1), unless no visible residue of drug substance can be seen in the vitreous cavity using indirect ophthalmoscopy.
  - Prior systemic or intravitreal treatment with VEGF Trap, ranibizumab (Lucentis) or bevacizumab (Avastin).
- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase II study.

Contacts/Locations

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Associated Retina Consultants

Phoenix, Arizona, United States, 85020

Retina Centers, PC
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United States, California

Retina Vitreous Associates Medical Group
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Loma Linda University Health Care
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United States, Georgia

Southeast Retina Center
Augusta, Georgia, United States, 30909

United States, Illinois

University of Chicago
Chicago, Illinois, United States, 60637

United States, Indiana

Midwest Eye Institute
Indianapolis, Indiana, United States, 46280

United States, Maryland

Johns Hopkins Hospital School of Medicine
Baltimore, Maryland, United States, 21287

United States, Massachusetts

Ophthalmic Consultants of Boston
Boston, Massachusetts, United States, 02114

New England Retina Consultants PC
West Springfield, Massachusetts, United States, 10189

United States, North Carolina

Charlotte Eye, Ear, Nose & Throat Asssociates

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Dean A. McGee Eye Institute
Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Retina Northwest PC
Portland, Oregon, United States, 97210

United States, Pennsylvania

Retina Diagnostic and Treatment Assoc., LLC
Philadelphia, Pennsylvania, United States, 19107

United States, South Dakota

Black Hills Regional Eye Institute
Rapid City, South Dakota, United States, 57701

United States, Tennessee

Retina-Vitreous Associates, P.C.
Nashville, Tennessee, United States, 37203

United States, Texas

Vitreoretinal Consultants Scurlock Tower Texas Medical Center
Houston, Texas, United States, 77030

Medical Center Ophthamology
San Antonio, Texas, United States, 78240

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00320788

Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Latest version (submitted January 27, 2012) on ClinicalTrials.gov

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- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
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- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	April 28, 2006	None (earliest Version on record)
2	○	○	August 1, 2006	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 3, 2006	Conditions, Study Description, Contacts/Locations, Eligibility, Outcome Measures, Study Status and Study Identification
4	◉	◉	July 24, 2007	Recruitment Status, Study Status and Contacts/Locations
5	○	○	January 23, 2009	Recruitment Status, Study Status, Arms and Interventions, Study Design, Contacts/Locations, Outcome Measures, Oversight, Sponsor/Collaborators and Study Identification
6	○	○	April 28, 2009	Study Status
7	○	○	November 30, 2010	Study Status
8	○	○	April 20, 2011	Study Status
9	○	○	December 1, 2011	Sponsor/Collaborators, Study Status
10	○	○	January 27, 2012	Arms and Interventions, Study Status, Outcome Measures, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, References, Contacts/Locations, Eligibility, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00320788

Submitted Date: July 24, 2007 (v4)

Study Identification

Unique Protocol ID: VGFT-OD-0508

Brief Title: Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Official Title:	A Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	July 2007
Overall Status:	Active, not recruiting
Study Start:	April 2006
Primary Completion:	
Study Completion:	
First Submitted:	April 28, 2006
First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	July 24, 2007
Last Update Posted:	July 26, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary: This study examines the effect of intravitreally administered VEGF Trap in patients with wet AMD.

The purpose of this trial is to assess the ocular and systemic safety and tolerability of repeated intravitreal doses of VEGF Trap in patients with subfoveal choroidal neovascularization (CNV) due to AMD.

Detailed Description: This is a double masked, prospective, randomized study in which five groups of approximately 30 patients meeting the eligibility criteria will be randomly assigned in a balanced ratio to receive a series of intravitreal (ITV) injections of VEGF Trap into the study eye at 4- or 12 -week intervals over a 12-week period.

After Week 12, patients will be evaluated every 4 weeks. Patients will remain on study or may be eligible to enter a long-term extension study, in which they will continue to receive VEGF Trap.

Conditions

Conditions: Macular Degeneration

Keywords: Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms:

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 150

Arms and Interventions

Intervention Details:

Drug: VEGF Trap

Outcome Measures

Primary Outcome Measures:

1. Safety, biological effect (optical coherence tomography [OCT], fluorescein angiography, visual acuity)

Secondary Outcome Measures:

2. Pharmacokinetics, immunogenicity, quality of life

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subfoveal CNV secondary to AMD.
- Central retinal (including lesion) thickness ≥ 300 µm as measured by OCT.
- Early Treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity of 73 letters to 34 letters.

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- Significant subfoveal atrophy or scarring.
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  - Subfoveal thermal laser therapy.
  - Submacular surgery or other surgical intervention for the treatment of AMD.
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Study Director

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Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Irvine, California, United States, 92697

Loma Linda, California, United States, 92354

Menlo Park, California, United States, 94025

Palm Springs, California, United States, 92262

United States, Florida

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Lakeland, Florida, United States, 33805

Oakland Park, Florida, United States, 33334

Orlando, Florida, United States, 32803

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Chicago, Illinois, United States, 60637

Glenview, Illinois, United States, 60025

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maryland

Baltimore, Maryland, United States, 21204

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

Peabody, Massachusetts, United States

West Springfield, Massachusetts, United States, 10189

United States, Michigan

Ann Arbor, Michigan, United States, 48105

United States, New Jersey

Toms River, New Jersey, United States, 08755

United States, New York

Great Neck, New York, United States, 11021

New York, New York, United States, 10032

United States, North Carolina

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

United States, Pennsylvania

Philadelphia, Pennsylvania, United States, 19107

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

United States, Wisconsin

Madison, Wisconsin, United States, 53705

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ClinicalTrials.gov archive

History of Changes for Study: NCT00320788

Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Latest version (submitted January 27, 2012) on ClinicalTrials.gov

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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	April 28, 2006	None (earliest Version on record)
2	○	○	August 1, 2006	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	◉	◉	October 3, 2006	Conditions, Study Description, Contacts/Locations, Eligibility, Outcome Measures, Study Status and Study Identification
4	○	○	July 24, 2007	Recruitment Status, Study Status and Contacts/Locations
5	○	○	January 23, 2009	Recruitment Status, Study Status, Arms and Interventions, Study Design, Contacts/Locations, Outcome Measures, Oversight, Sponsor/Collaborators and Study Identification
6	○	○	April 28, 2009	Study Status
7	○	○	November 30, 2010	Study Status
8	○	○	April 20, 2011	Study Status
9	○	○	December 1, 2011	Sponsor/Collaborators, Study Status
10	○	○	January 27, 2012	Arms and Interventions, Study Status, Outcome Measures, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, References, Contacts/Locations, Eligibility, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320788

Submitted Date: October 3, 2006 (v3)

Study Identification

Unique Protocol ID: VGFT-OD-0508

Brief Title: Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Official Title:	A Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	August 2006
Overall Status:	Recruiting
Study Start:	April 2006
Primary Completion:	
Study Completion:	
First Submitted:	April 28, 2006
First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	October 3, 2006
Last Update Posted:	October 4, 2006 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary: This study examines the effect of intravitreally administered VEGF Trap in patients with wet AMD.

The purpose of this trial is to assess the ocular and systemic safety and tolerability of repeated intravitreal doses of VEGF Trap in patients with subfoveal choroidal neovascularization (CNV) due to AMD.

Detailed Description: This is a double masked, prospective, randomized study in which five groups of approximately 30 patients meeting the eligibility criteria will be randomly assigned in a balanced ratio to receive a series of intravitreal (ITV) injections of VEGF Trap into the study eye at 4- or 12 -week intervals over a 12-week period.

After Week 12, patients will be evaluated every 4 weeks. Patients will remain on study or may be eligible to enter a long-term extension study, in which they will continue to receive VEGF Trap.

Conditions

Conditions: Macular Degeneration

Keywords: Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms:

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 150

Arms and Interventions

Intervention Details:

Drug: VEGF Trap

Outcome Measures

Primary Outcome Measures:

1. Safety, biological effect (optical coherence tomography [OCT], fluorescein angiography, visual acuity)

Secondary Outcome Measures:

2. Pharmacokinetics, immunogenicity, quality of life

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subfoveal CNV secondary to AMD.
- Central retinal (including lesion) thickness ≥ 300 µm as measured by OCT.
- Early Treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity of 73 letters to 34 letters.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Day 1.
- Aphakia.
- Significant subfoveal atrophy or scarring.
- Prior treatment with the following in the study eye:
  - Subfoveal thermal laser therapy.
  - Submacular surgery or other surgical intervention for the treatment of AMD.
  - Extrafoveal laser coagulation treatment within 12 weeks prior to Day 1.
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  - Pegaptanib sodium (Macugen) within 8 weeks of Visit 2 (Day 1).

- Juxtascleral steroids or anecortave acetate within 24 weeks (6 months) prior to Visit 2 (Day 1).
- Intravitreal administration of triamcinolone acetonide or other steroids within 24 weeks prior to Visit 2 (Day 1), unless no visible residue of drug substance can be seen in the vitreous cavity using indirect ophthalmoscopy.
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- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase II study.

Contacts/Locations

Central Contact: Regeneron
Email: VEGF.Trap@regeneron.com

Locations: **United States, Arizona**

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Not yet recruiting]
Irvine, California, United States, 92697

[Not yet recruiting]
Loma Linda, California, United States, 92354

[Not yet recruiting]
Menlo Park, California, United States, 94025

[Recruiting]

Palm Springs, California, United States, 92262

United States, Florida

[Recruiting]
Ft. Myers, Florida, United States, 33912

[Recruiting]
Lakeland, Florida, United States, 33805

[Recruiting]
Oakland Park, Florida, United States, 33334

[Not yet recruiting]
Orlando, Florida, United States, 32803

United States, Georgia

[Recruiting]
Augusta, Georgia, United States, 30909

United States, Illinois

[Not yet recruiting]
Chicago, Illinois, United States, 60637

[Not yet recruiting]
Glenview, Illinois, United States, 60025

United States, Indiana

[Recruiting]
Indianapolis, Indiana, United States, 46280

United States, Maryland

[Not yet recruiting]
Baltimore, Maryland, United States, 21204

[Recruiting]
Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

[Recruiting]

Peabody, Massachusetts, United States

[Recruiting]

West Springfield, Massachusetts, United States, 10189

United States, Michigan

[Not yet recruiting]

Ann Arbor, Michigan, United States, 48105

United States, New Jersey

[Recruiting]

Toms River, New Jersey, United States, 08755

United States, New York

[Not yet recruiting]

Great Neck, New York, United States, 11021

[Recruiting]

New York, New York, United States, 10032

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

[Not yet recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]

Portland, Oregon, United States, 97210

United States, Pennsylvania

[Not yet recruiting]

Philadelphia, Pennsylvania, United States, 19107

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Wisconsin

[Not yet recruiting]

Madison, Wisconsin, United States, 53705

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ClinicalTrials.gov archive

History of Changes for Study: NCT00320788

Safety and Efficacy of Repeated Intravitreal Administration of VEGF Trap in Patients With Wet AMD

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10	○	○	January 27, 2012	Arms and Interventions, Study Status, Outcome Measures, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, References, Contacts/Locations, Eligibility, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320788

Submitted Date: August 1, 2006 (v2)

Study Identification

Unique Protocol ID: VGFT-OD-0508

Brief Title: Safety and Efficacy of Repeated Intravitreal Administration of VEGF Trap in Patients With Wet AMD

Official Title: A Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification:	August 2006
Overall Status:	Recruiting
Study Start:	April 2006
Primary Completion:	
Study Completion:	
First Submitted:	April 28, 2006
First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	August 1, 2006
Last Update Posted:	August 3, 2006 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary:	The effect of intravitreally administered VEGF Trap in patients with wet AMD.

To assess the ocular and systemic safety and tolerability of repeated intravitreal doses of VEGF Trap in patients with subfoveal choroidal neovascularization (CNV) due to AMD.

Detailed Description: This is a double masked, prospective, randomized study in which five groups of approximately 30 patients meeting the eligibility criteria will be randomly assigned in a balanced ratio to receive a series of ITV injections of VEGF Trap into the study eye at 4- or 12 -week intervals over a 12-week period.

After Week 12, patients will be evaluated every 4 weeks. Patients will remain on study or may be eligible to enter a long-term extension study, in which they will continue to receive VEGF Trap.

Conditions

Conditions: Neovascular Age-Related Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms:

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 150

Arms and Interventions

Intervention Details:

Drug: VEGF Trap

Outcome Measures

Primary Outcome Measures:

1. Safety, biological effect (OCT, fluorescein angiography, visual acuity)

Secondary Outcome Measures:

2. Pharmacokinetics, immunogenicity, quality of life

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subfoveal CNV secondary to AMD.
- Central retinal (including lesion) thickness ≥ 300 µm as measured by OCT.
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Beverly Hills, California, United States, 90211

[Not yet recruiting]
Irvine, California, United States, 92697

[Not yet recruiting]
Loma Linda, California, United States, 92354

[Not yet recruiting]
Menlo Park, California, United States, 94025

[Recruiting]
Palm Springs, California, United States, 92262

United States, Florida

[Recruiting]
Ft. Myers, Florida, United States, 33912

[Recruiting]

Lakeland, Florida, United States, 33805

[Recruiting]

Oakland Park, Florida, United States, 33334

[Not yet recruiting]

Orlando, Florida, United States, 32803

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Illinois

[Not yet recruiting]

Chicago, Illinois, United States, 60637

[Not yet recruiting]

Glenview, Illinois, United States, 60025

United States, Indiana

[Recruiting]

Indianopolis, Indiana, United States, 46280

United States, Maryland

[Not yet recruiting]

Baltimore, Maryland, United States, 21204

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

[Recruiting]

Peabody, Massachusetts, United States

[Recruiting]

West Springfield, Massachusetts, United States, 10189

United States, Michigan

[Not yet recruiting]

Ann Arbor, Michigan, United States, 48105

United States, New Jersey

[Recruiting]

Toms River, New Jersey, United States, 08755

United States, New York

[Not yet recruiting]

Great Neck, New York, United States, 11021

[Recruiting]

New York, New York, United States, 10032

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

[Not yet recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]

Portland, Oregon, United States, 97210

United States, Pennsylvania

[Not yet recruiting]

Philadelphia, Pennsylvania, United States, 19107

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Wisconsin

[Not yet recruiting]

Madison, Wisconsin, United States, 53705

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00320788

Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Latest version (submitted January 27, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	April 28, 2006	None (earliest Version on record)
2	○	○	August 1, 2006	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
3	○	○	October 3, 2006	Conditions, Study Description, Contacts/Locations, Eligibility, Outcome Measures, Study Status and Study Identification
4	○	○	July 24, 2007	Recruitment Status, Study Status and Contacts/Locations
5	○	○	January 23, 2009	Recruitment Status, Study Status, Arms and Interventions, Study Design, Contacts/Locations, Outcome Measures, Oversight, Sponsor/Collaborators and Study Identification
6	○	○	April 28, 2009	Study Status
7	○	○	November 30, 2010	Study Status
8	○	○	April 20, 2011	Study Status
9	○	○	December 1, 2011	Sponsor/Collaborators, Study Status
10	◉	◉	January 27, 2012	Arms and Interventions, Study Status, Outcome Measures, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, References, Contacts/Locations, Eligibility, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00320788

Submitted Date: January 27, 2012 (v10)

Study Identification

Unique Protocol ID: VGFT-OD-0508

Brief Title: Safety and Efficacy of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor (VEGF) Trap in Patients With Wet Age-Related Macular Degeneration (AMD)

Official Title:	A Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap in Patients With Neovascular Age-Related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	January 2012
Overall Status:	Completed
Study Start:	April 2006
Primary Completion:	June 2008 [Actual]
Study Completion:	August 2008 [Actual]
First Submitted:	April 28, 2006
First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	January 27, 2012
Results First Posted:	March 1, 2012 [Estimate]
Certification/Extension First Submitted:	November 30, 2010
Certification/Extension First Submitted that Met QC Criteria:	November 30, 2010
Certification/Extension First Posted:	December 2, 2010 [Estimate]
Last Update Submitted that	January 27, 2012

Met QC Criteria:	
Last Update Posted:	March 1, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary: This study examines the effect of intravitreally administered VEGF Trap in patients with wet AMD.

The purpose of this trial is to assess the ocular and systemic safety and tolerability of repeated intravitreal doses of VEGF Trap in patients with subfoveal choroidal neovascularization (CNV) due to AMD.

Detailed Description: This is a double masked, prospective, randomized study in which five groups of approximately 30 patients meeting the eligibility criteria will be randomly assigned in a balanced ratio to receive a series of intravitreal (IVT) injections of VEGF Trap into the study eye at 4- or 12 -week intervals over a 12-week period.

After Week 12, patients will be evaluated every 4 weeks. Patients will remain on study or may be eligible to enter a long-term extension study, in which they will continue to receive VEGF Trap.

Conditions

Conditions:	Macular Degeneration
Keywords:	Neovascular Age-Related Macular Degeneration

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Triple (Participant, Care Provider, Investigator)
Allocation:	Randomized
Enrollment:	159 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: aflibercept injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received 0.5 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 4 week intervals through Week 12 Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q12	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received 0.5 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12. Other Names: • VEGF Trap-Eye • BAY86-5321

Arms	Assigned Interventions
Experimental: aflibercept injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received 2.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 4 week intervals through Week 12 Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q12	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received 2.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection (VEGF Trap-Eye, BAY86-5321) 4.0mg q12	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received 4.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12. Other Names: • VEGF Trap-Eye • BAY86-5321

Outcome Measures

[See Results Section]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subfoveal CNV secondary to AMD.
- Central retinal (including lesion) thickness ≥ 300 µm as measured by Optical Coherence Tomography (OCT).
- Early Treatment of Diabetic Retinopathy Study (ETDRS) best-corrected visual acuity of 73 letters to 34 letters.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Day 1.
- Aphakia.
- Significant subfoveal atrophy or scarring.
- Prior treatment with the following in the study eye:
  - Subfoveal thermal laser therapy.
  - Submacular surgery or other surgical intervention for the treatment of AMD.
  - Extrafoveal laser coagulation treatment within 12 weeks prior to Day 1.
  - Photodynamic therapy (PDT) within 12 weeks prior to Visit 2 (Day 1).
  - Pegaptanib sodium (Macugen) within 8 weeks of Visit 2 (Day 1).
  - Juxtascleral steroids or anecortave acetate within 24 weeks (6 months) prior to Visit 2 (Day 1).
  - Intravitreal administration of triamcinolone acetonide or other steroids within 24 weeks prior to Visit 2 (Day 1), unless no visible residue of drug substance can be seen in the vitreous cavity using indirect ophthalmoscopy.
  - Prior systemic or intravitreal treatment with VEGF Trap, ranibizumab (Lucentis) or bevacizumab (Avastin).
- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase II study.

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Associated Retina Consultants
Phoenix, Arizona, United States, 85020

Retina Centers, PC
Tucson, Arizona, United States, 85704

United States, California

Retina Vitreous Associates Medical Group
Beverly Hills, California, United States, 90211

Loma Linda University Health Care
Loma Linda, California, United States, 92354

United States, Georgia

Southeast Retina Center
Augusta, Georgia, United States, 30909

United States, Illinois

University of Chicago
Chicago, Illinois, United States, 60637

United States, Indiana

Midwest Eye Institute
Indianapolis, Indiana, United States, 46280

United States, Maryland

Johns Hopkins Hospital School of Medicine
Baltimore, Maryland, United States, 21287

United States, Massachusetts

Ophthalmic Consultants of Boston

Boston, Massachusetts, United States, 02114

New England Retina Consultants PC

West Springfield, Massachusetts, United States, 10189

United States, North Carolina

Charlotte Eye, Ear, Nose & Throat Asssociates

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Dean A. McGee Eye Institute

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Retina Northwest PC

Portland, Oregon, United States, 97210

United States, Pennsylvania

Retina Diagnostic and Treatment Assoc., LLC

Philadelphia, Pennsylvania, United States, 19107

United States, South Dakota

Black Hills Regional Eye Institute

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Retina-Vitreous Associates, P.C.

Nashville, Tennessee, United States, 37203

United States, Texas

Vitreoretinal Consultants Scurlock Tower Texas Medical Center

Houston, Texas, United States, 77030

Medical Center Ophthamology

San Antonio, Texas, United States, 78240

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Plan to Share IPD:

References

Citations:

Links: URL: http://www.ncbi.nlm.nih.gov/pubmed/21640257
Description: Primary endpoint results of a phase II study of vascular endothelial growth factor trap-eye in wet age-related macular degeneration.

URL: http://www.ncbi.nlm.nih.gov/pubmed/21640258
Description: The 1-year results of CLEAR-IT 2, a phase 2 study of vascular endothelial growth factor trap-eye dosed as-needed after 12-week fixed dosing.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 29 study sites in the United States. Recruitment period: May 2006 to April 2007.
Pre-assignment Details	A total of 301 participants were screened; 159 participants were randomized; 157 participants were included in both the Safety Analysis Set (SAF) and the Full Analysis Set (FAS) as all received study treatment, had baseline assessments and at least 1 post-baseline assessment.

Reporting Groups

	Description
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q4	Participants received 0.5 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 4 week intervals through Week 12.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q12	Participants received 0.5 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12.

Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q4	Participants received 2.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 4 week intervals through Week 12.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q12	Participants received 2.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 4.0mg q12	Participants received 4.0 mg of aflibercept injection (VEGF Trap-Eye, BAY86-5321) at 12 week intervals through Week 12.

Overall Study

	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q4	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg q12	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q4	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg q12	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 4.0mg q12
Started	32	32	32	32 [1]	31
Participants Received Treatment (SAF)	32	32	31 [2]	31 [2]	31
Completed	26	26	29	27	26
Not Completed	6	6	3	5	5
Adverse Event	0	0	0	1	0
Death	0	0	1	0	1
Lost to Follow-up	0	2	1	0	0
Decision by the Sponsor	1	1	0	0	1
Other	1	2	1	1	1
Physician Decision	1	1	0	0	0
Protocol Violation	0	0	0	0	1
Withdrawal by Subject	3	0	0	3	1

[1] Participants Randomized

[2] One participant in this group did not receive treatment and was not included in the SAF and FAS

Baseline Characteristics

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.

Baseline Measures

		Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants		32	32	31	31	31	157
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
		79.6 (0 to 0)	78.5 (0 to 0)	74.9 (0 to 0)	79.6 (0 to 0)	78.3 (0 to 0)	78.2 (0 to 0)
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
	Female	17 53.12% (0 to 0)	25 78.12% (0 to 0)	20 64.52% (0 to 0)	16 51.61% (0 to 0)	20 64.52% (0 to 0)	98 62.42%
	Male	15 46.88% (0 to 0)	7 21.88% (0 to 0)	11 35.48% (0 to 0)	15 48.39% (0 to 0)	11 35.48% (0 to 0)	59 37.58%

		Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Ethnicity (NIH/OMB) Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
	Hispanic or Latino	0 0% (0 to 0)	1 3.12% (0 to 0)	2 6.45% (0 to 0)	1 3.23% (0 to 0)	0 0% (0 to 0)	4 2.55%
	Not Hispanic or Latino	32 100% (0 to 0)	31 96.88% (0 to 0)	29 93.55% (0 to 0)	30 96.77% (0 to 0)	31 100% (0 to 0)	153 97.45%
	Unknown or Not Reported	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
Race (NIH/OMB) Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
	American Indian or Alaska Native	0 0% (0 to 0)	0 0% (0 to 0)	1 3.23% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.64%
	Asian	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
	Native Hawaiian or Other Pacific Islander	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
	Black or African American	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
	White	32 100% (0 to 0)	32 100% (0 to 0)	30 96.77% (0 to 0)	31 100% (0 to 0)	31 100% (0 to 0)	156 99.36%

		Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
	More than one race	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
	Unknown or Not Reported	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
Central Retinal/Lesion Thickness (CR/LT) Mean (Standard Deviation) Unit of measure: µm	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
		442.2 (0 to 0)	442.6 (0 to 0)	453.3 (0 to 0)	447.0 (0 to 0)	497.5 (0 to 0)	456.4 (0 to 0)
Best Corrected Visual Acuity (BCVA) [1] Mean (Standard Deviation) Unit of measure: letters read	Number Analyzed	32 Participants	32 Participants	31 Participants	31 Participants	31 Participants	157 Participants
		54.1 (0 to 0)	55.6 (0 to 0)	57.9 (0 to 0)	57.2 (0 to 0)	53.0 (0 to 0)	55.5 (0 to 0)
		[1] Measure Description: BCVA as Measured by 4 Meter Early Treatment Diabetic Retinopathy Study (ETDRS)eye charts/measures					

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change of CR/LT From Baseline at Week 12
Measure Description	CR/LT measured in micrometers (µm); lower individual values represent better outcomes.
Time Frame	Baseline and at Week 12

Analysis Population Description

Full Analysis Set (FAS) used for analysis, Last Observation Carried Forward (LOCF)

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Mean Change of CR/LT From Baseline at Week 12 Measure Type: Mean (Standard Deviation) Unit of Measure: µm	-153.5 (0 to 0)	-75.6 (0 to 0)	-169.2 (0 to 0)	-56.3 (0 to 0)	-139.8 (0 to 0)	-118.8 (0 to 0)

2. Secondary Outcome Measure:

Measure Title	Mean Percent Change of CR/LT From Baseline at Week 12
Measure Description	CR/LT measured in micrometers (µm); a more negative percentage represents a better outcome
Time Frame	Baseline and at Week 12

Analysis Population Description

FAS used for analysis, LOCF

Reporting Groups

	Description

Aflibercept Injection 0.5mg q4	Participants received 0.5mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Mean Percent Change of CR/LT From Baseline at Week 12 Measure Type: Mean (Standard Deviation) Unit of Measure: percent change	-32.4 (0 to 0)	-15.2 (0 to 0)	-33.2 (0 to 0)	-10.3 (0 to 0)	-21.1 (0 to 0)	-22.5 (0 to 0)

3. Secondary Outcome Measure:

Measure Title	Mean Change in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) From Baseline at Week 12
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning
Time Frame	Baseline and at week 12

Analysis Population Description

FAS used for analysis, LOCF

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Mean Change in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) From Baseline at Week 12 Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	8.8 (0 to 0)	3.8 (0 to 0)	8.3 (0 to 0)	5.2 (0 to 0)	2.6 (0 to 0)	5.7 (0 to 0)

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score From Baseline at Week 12
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning
Time Frame	At Week 12

Analysis Population Description

FAS used for analysis, LOCF

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score From Baseline at Week 12 Measure Type: Number Unit of Measure: percentage of participants	18.8 (0 to 0)	21.9 (0 to 0)	25.8 (0 to 0)	16.1 (0 to 0)	9.7 (0 to 0)	18.5 (0 to 0)

5. Post-Hoc Outcome Measure:

Measure Title	Mean Change of CR/LT From Baseline at Week 16
Measure Description	CR/LT measured in micrometers (µm); lower individual values represent better outcomes
Time Frame	Baseline and at Week 16

Analysis Population Description

FAS used for analysis, LOCF

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Mean Change of CR/LT From Baseline at Week 16 Measure Type: Mean (Standard Deviation) Unit of Measure: µm	-163.3 (0 to 0)	-139.6 (0 to 0)	-182.7 (0 to 0)	-107.4 (0 to 0)	-208.6 (0 to 0)	-160.2 (0 to 0)

6. Post-Hoc Outcome Measure:

Measure Title	Mean Change in BCVA as Measured by ETDRS From Baseline at Week 16
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning
Time Frame	Baseline and at Week 16

Analysis Population Description

FAS used for analysis, LOCF

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.
Total	

Measured Values

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12	Total
Overall Number of Participants Analyzed	32	32	31	31	31	157
Mean Change in BCVA as Measured by ETDRS From Baseline at Week 16 Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	9.3 (0 to 0)	5.6 (0 to 0)	10.0 (0 to 0)	4.3 (0 to 0)	3.9 (0 to 0)	6.6 (0 to 0)

Reported Adverse Events

Time Frame	Adverse events (AEs) considered related to study treatment were followed until resolution or until the event was considered chronic or stable.
Adverse Event Reporting Description	Safety was assessed through reported AEs, clinical laboratory test results, vital signs, and ophthalmic examinations

Reporting Groups

	Description
Aflibercept Injection 0.5mg q4	Participants received 0.5 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 0.5mg q12	Participants received 0.5 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 2.0mg q4	Participants received 2.0 mg of aflibercept injection at 4 week intervals through Week 12.
Aflibercept Injection 2.0mg q12	Participants received 2.0 mg of aflibercept injection at 12 week intervals through Week 12.
Aflibercept Injection 4.0mg q12	Participants received 4.0 mg of aflibercept injection at 12 week intervals through Week 12.

All-Cause Mortality

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/	/

Serious Adverse Events

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	11/	5/	10/	7/	2/
Cardiac disorders					
ANGINA PECTORIS [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
ATRIAL FIBRILLATION [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
ATRIOVENTRICULAR BLOCK COMPLETE [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
BRADYCARDIA [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
CARDIAC FAILURE CONGESTIVE [A†]	1/32 (3.12%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
CORONARY ARTERY DISEASE [A†]	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
Eye disorders					
RETINAL DETACHMENT [A [1]†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
UVEITIS [A [2]†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
VISUAL ACUITY REDUCED [A [1]†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Gastrointestinal disorders					
DYSKINESIA OESOPHAGEAL [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
INTESTINAL OBSTRUCTION [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
SMALL INTESTINAL OBSTRUCTION [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
VOLVULUS [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
General disorders					
ASTHENIA [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
NON-CARDIAC CHEST PAIN [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Infections and infestations					
BRONCHITIS [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	1/31 (3.23%)	0/31 (0%)
CELLULITIS [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
GASTROENTERITIS [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
PNEUMONIA [A†]	2/32 (6.25%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
URINARY TRACT INFECTION [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	1/31 (3.23%)	0/31 (0%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
Injury, poisoning and procedural complications					
FALL [A†]	1/32 (3.12%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
HIP FRACTURE [A†]	0/32 (0%)	1/32 (3.12%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
SKIN LACERATION [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)
SYNOVIAL RUPTURE [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Investigations					
INTRAOCULAR PRESSURE INCREASED [A [1]†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
Musculoskeletal and connective tissue disorders					
BACK PAIN [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
OSTEOARTHRITIS [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
SPINAL OSTEOARTHRITIS [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
BRAIN NEOPLASM MALIGNANT [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
COLON CANCER [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
METASTASES TO LUNG [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)
NON-HODGKIN'S LYMPHOMA [A†]	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
PANCREATIC CARCINOMA [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
SQUAMOUS CELL CARCINOMA [A†]	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
THYROID NEOPLASM [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
TRANSITIONAL CELL CARCINOMA A†	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)
Nervous system disorders					
CAROTID ARTERY OCCLUSION A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
CEREBROVASCULAR ACCIDENT A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
COORDINATION ABNORMAL A†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
DYSARTHRIA A†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
SPINAL CORD DISORDER A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
TRANSIENT ISCHAEMIC ATTACK A†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
Renal and urinary disorders					
RENAL FAILURE A†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
STRESS INCONTINENCE A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
URINARY RETENTION A†	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Respiratory, thoracic and mediastinal disorders					
CHRONIC OBSTRUCTIVE PULMONARY DISEASE A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
PNEUMONIA ASPIRATION A†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
PULMONARY EMBOLISM A†	0/32 (0%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	0/31 (0%)
PULMONARY HYPERTENSION A†	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
Surgical and medical procedures					
PILONIDAL SINUS REPAIR A†	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Vascular disorders					
DEEP VEIN THROMBOSIS A†	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	0/31 (0%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

[1] Fellow Eye

[2] Study Eye

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	26/	25/	27/	22/	22/
Blood and lymphatic system disorders					
ANAEMIA A†	0/32 (0%)	1/32 (3.12%)	3/31 (9.68%)	0/31 (0%)	0/31 (0%)
Cardiac disorders					
ANGINA PECTORIS A†	2/32 (6.25%)	0/32 (0%)	1/31 (3.23%)	1/31 (3.23%)	0/31 (0%)
BRADYCARDIA A†	1/32 (3.12%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
Eye disorders					
BLEPHARITIS A [1]†	2/32 (6.25%)	0/32 (0%)	2/31 (6.45%)	3/31 (9.68%)	1/31 (3.23%)
CATARACT A [1]†	0/32 (0%)	1/32 (3.12%)	1/31 (3.23%)	1/31 (3.23%)	2/31 (6.45%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
CATARACT NUCLEAR [A] [1]†	3/32 (9.38%)	0/32 (0%)	2/31 (6.45%)	1/31 (3.23%)	0/31 (0%)
CATARACT SUBCAPSULAR [A] [1]†	0/32 (0%)	2/32 (6.25%)	0/31 (0%)	1/31 (3.23%)	2/31 (6.45%)
CHOROIDAL NEOVASCULARISATION [A] [1]†	0/32 (0%)	1/32 (3.12%)	2/31 (6.45%)	1/31 (3.23%)	0/31 (0%)
CONJUNCTIVAL HAEMORRHAGE [A] [1]†	2/32 (6.25%)	0/32 (0%)	2/31 (6.45%)	2/31 (6.45%)	1/31 (3.23%)
DETACHMENT OF RETINAL PIGMENT EPITHELIUM [A] [1]†	2/32 (6.25%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
DRY EYE [A] [1]†	1/32 (3.12%)	0/32 (0%)	1/31 (3.23%)	2/31 (6.45%)	0/31 (0%)
EYE INFLAMMATION [A] [2]†	2/32 (6.25%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	1/31 (3.23%)
EYE IRRITATION [A] [2]†	5/32 (15.62%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	1/31 (3.23%)
EYE PAIN [A] [2]†	5/32 (15.62%)	2/32 (6.25%)	4/31 (12.9%)	1/31 (3.23%)	3/31 (9.68%)
FOREIGN BODY SENSATION IN EYES [A] [2]†	3/32 (9.38%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
LACRIMATION DECREASED [A] [2]†	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	2/31 (6.45%)
LACRIMATION INCREASED [A] [1]†	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	2/31 (6.45%)
MACULAR DEGENERATION [A] [2]†	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	2/31 (6.45%)
MACULOPATHY [A] [2]†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	2/31 (6.45%)	1/31 (3.23%)
PHOTOPSIA [A] [2]†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	2/31 (6.45%)	3/31 (9.68%)
PUNCTATE KERATITIS [A] [2]†	0/32 (0%)	0/32 (0%)	1/31 (3.23%)	2/31 (6.45%)	2/31 (6.45%)
REFRACTION DISORDER [A] [1]†	1/32 (3.12%)	4/32 (12.5%)	1/31 (3.23%)	1/31 (3.23%)	3/31 (9.68%)
RETINAL DEPIGMENTATION [A] [2]†	2/32 (6.25%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
RETINAL HAEMORRHAGE [A] [1]†	0/32 (0%)	2/32 (6.25%)	1/31 (3.23%)	3/31 (9.68%)	0/31 (0%)
RETINAL OEDEMA [A] [1]†	1/32 (3.12%)	2/32 (6.25%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
RETINAL PIGMENT EPITHELIOPATHY [A] [1]†	2/32 (6.25%)	3/32 (9.38%)	0/31 (0%)	1/31 (3.23%)	1/31 (3.23%)
SUBRETINAL FIBROSIS [A] [2]†	2/32 (6.25%)	1/32 (3.12%)	1/31 (3.23%)	2/31 (6.45%)	2/31 (6.45%)
VISION BLURRED [A] [2]†	2/32 (6.25%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
VISUAL ACUITY REDUCED [A] [1]†	1/32 (3.12%)	1/32 (3.12%)	4/31 (12.9%)	1/31 (3.23%)	1/31 (3.23%)
VISUAL DISTURBANCE [A] [2]†	2/32 (6.25%)	1/32 (3.12%)	0/31 (0%)	2/31 (6.45%)	3/31 (9.68%)
VITREOUS DETACHMENT [A] [1]†	4/32 (12.5%)	1/32 (3.12%)	2/31 (6.45%)	3/31 (9.68%)	4/31 (12.9%)
VITREOUS FLOATERS [A] [1]†	2/32 (6.25%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	1/31 (3.23%)
Gastrointestinal disorders					
CONSTIPATION [A]†	5/32 (15.62%)	1/32 (3.12%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
DIARRHOEA [A]†	1/32 (3.12%)	1/32 (3.12%)	0/31 (0%)	1/31 (3.23%)	2/31 (6.45%)
FLATULENCE [A]†	0/32 (0%)	2/32 (6.25%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
NAUSEA [A]†	3/32 (9.38%)	0/32 (0%)	0/31 (0%)	1/31 (3.23%)	1/31 (3.23%)
General disorders					
CHEST PAIN [A]†	2/32 (6.25%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Immune system disorders					
SEASONAL ALLERGY [A]†	4/32 (12.5%)	2/32 (6.25%)	0/31 (0%)	0/31 (0%)	1/31 (3.23%)
Infections and infestations					
BRONCHITIS [A]†	5/32 (15.62%)	2/32 (6.25%)	1/31 (3.23%)	1/31 (3.23%)	3/31 (9.68%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
CELLULITIS [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	2/31 (6.45%)	1/31 (3.23%)
CYSTITIS [A†]	2/32 (6.25%)	0/32 (0%)	1/31 (3.23%)	1/31 (3.23%)	0/31 (0%)
GASTROENTERITIS VIRAL [A†]	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	1/31 (3.23%)
HERPES ZOSTER [A†]	0/32 (0%)	2/32 (6.25%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
INFLUENZA [A†]	0/32 (0%)	2/32 (6.25%)	2/31 (6.45%)	0/31 (0%)	2/31 (6.45%)
NASOPHARYNGITIS [A†]	3/32 (9.38%)	1/32 (3.12%)	3/31 (9.68%)	1/31 (3.23%)	2/31 (6.45%)
PNEUMONIA [A†]	3/32 (9.38%)	0/32 (0%)	2/31 (6.45%)	1/31 (3.23%)	1/31 (3.23%)
RHINOVIRUS INFECTION [A†]	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
SINUSITIS [A†]	2/32 (6.25%)	1/32 (3.12%)	2/31 (6.45%)	1/31 (3.23%)	3/31 (9.68%)
TOOTH ABSCESS [A†]	1/32 (3.12%)	1/32 (3.12%)	1/31 (3.23%)	2/31 (6.45%)	0/31 (0%)
UPPER RESPIRATORY TRACT INFECTION [A†]	3/32 (9.38%)	1/32 (3.12%)	2/31 (6.45%)	6/31 (19.35%)	3/31 (9.68%)
URINARY TRACT INFECTION [A†]	1/32 (3.12%)	3/32 (9.38%)	6/31 (19.35%)	1/31 (3.23%)	2/31 (6.45%)
VULVOVAGINAL MYCOTIC INFECTION [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	2/31 (6.45%)	1/31 (3.23%)
Injury, poisoning and procedural complications					
FALL [A†]	2/32 (6.25%)	1/32 (3.12%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
JOINT SPRAIN [A†]	0/32 (0%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	2/31 (6.45%)
Investigations					
BLOOD CREATININE INCREASED [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	2/31 (6.45%)	1/31 (3.23%)
BLOOD GLUCOSE INCREASED [A†]	0/32 (0%)	2/32 (6.25%)	1/31 (3.23%)	1/31 (3.23%)	0/31 (0%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
BLOOD UREA INCREASED [A†]	0/32 (0%)	1/32 (3.12%)	0/31 (0%)	2/31 (6.45%)	0/31 (0%)
INTRAOCULAR PRESSURE INCREASED [A [1]†]	1/32 (3.12%)	3/32 (9.38%)	3/31 (9.68%)	2/31 (6.45%)	1/31 (3.23%)
Metabolism and nutrition disorders					
DEHYDRATION [A†]	1/32 (3.12%)	1/32 (3.12%)	2/31 (6.45%)	0/31 (0%)	1/31 (3.23%)
GOUT [A†]	1/32 (3.12%)	2/32 (6.25%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
HYPERCHOLESTEROLAEMIA [A†]	4/32 (12.5%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
Musculoskeletal and connective tissue disorders					
BACK PAIN [A†]	1/32 (3.12%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
OSTEOARTHRITIS [A†]	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	1/31 (3.23%)
Nervous system disorders					
DEMENTIA ALZHEIMER'S TYPE [A†]	0/32 (0%)	2/32 (6.25%)	0/31 (0%)	0/31 (0%)	0/31 (0%)
DIZZINESS [A†]	1/32 (3.12%)	0/32 (0%)	2/31 (6.45%)	1/31 (3.23%)	0/31 (0%)
HEADACHE [A†]	1/32 (3.12%)	3/32 (9.38%)	1/31 (3.23%)	0/31 (0%)	1/31 (3.23%)
SINUS HEADACHE [A†]	1/32 (3.12%)	2/32 (6.25%)	2/31 (6.45%)	0/31 (0%)	2/31 (6.45%)
Psychiatric disorders					
ANXIETY [A†]	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
DEPRESSION [A†]	0/32 (0%)	1/32 (3.12%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)
INSOMNIA [A†]	2/32 (6.25%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	0/31 (0%)
Respiratory, thoracic and mediastinal disorders					
COUGH [A†]	2/32 (6.25%)	1/32 (3.12%)	2/31 (6.45%)	1/31 (3.23%)	2/31 (6.45%)

	Aflibercept Injection 0.5mg q4	Aflibercept Injection 0.5mg q12	Aflibercept Injection 2.0mg q4	Aflibercept Injection 2.0mg q12	Aflibercept Injection 4.0mg q12
DYSPNOEA A†	2/32 (6.25%)	0/32 (0%)	1/31 (3.23%)	2/31 (6.45%)	0/31 (0%)
PHARYNGOLARYNGEAL PAIN A†	1/32 (3.12%)	0/32 (0%)	0/31 (0%)	0/31 (0%)	2/31 (6.45%)
Skin and subcutaneous tissue disorders					
RASH A†	2/32 (6.25%)	0/32 (0%)	1/31 (3.23%)	0/31 (0%)	1/31 (3.23%)
Vascular disorders					
HYPERTENSION A†	6/32 (18.75%)	1/32 (3.12%)	2/31 (6.45%)	0/31 (0%)	3/31 (9.68%)
HYPOTENSION A†	0/32 (0%)	0/32 (0%)	2/31 (6.45%)	0/31 (0%)	0/31 (0%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA 10.0

[1] Fellow Eye

[2] Study Eye

Limitations and Caveats

This is a phase 2 study with small numbers of patients per group limiting the conclusions that can be drawn from the resulting data.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals, Inc.
Phone:
Email: clinicaltrials@regeneron.com

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ClinicalTrials.gov archive

History of Changes for Study: NCT00320814

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Latest version (submitted June 8, 2011) on ClinicalTrials.gov

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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	April 28, 2006	None (earliest Version on record)
2	○	○	September 6, 2006	Recruitment Status, Study Status and Contacts/Locations
3	○	○	January 5, 2009	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Oversight, Contacts/Locations, Study Design and Sponsor/Collaborators

Version	A	B	Submitted Date	Changes
4	○	○	January 25, 2011	Study Status
5	◉	◉	June 8, 2011	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320814

Submitted Date: June 8, 2011 (v5)

Study Identification

Unique Protocol ID: VGFT-OD-0512

Brief Title: Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Official Title: An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema

Secondary IDs:

Study Status

Record Verification: June 2011

Overall Status: Completed

Study Start: April 2006

Primary Completion: August 2006 [Actual]

Study Completion: August 2007 [Actual]

First Submitted: April 28, 2006

First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	June 8, 2011
Last Update Posted:	June 10, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema.
Detailed Description:	This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 5 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1	Drug: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1

Outcome Measures

Primary Outcome Measures:

1. To assess the ocular and systemic safety and tolerability of a single intravitreal (IVT) injection of VEGF Trap-Eye in patients with diabetic macular edema (DME)
   Assessments for safety and tolerablity are performed at each visit (Visit 1 - Visit 10)

Secondary Outcome Measures:

2. To obtain a preliminary assessment of the effect of a single dose of VEGF Trap-Eye on central retinal thickness (CRT) at the center point as determined by optical coherence tomography (OCT)
   Assessments for CRT are performed at each visit (Visit 1 - Visit 10) by means of OCT.
3. To obtain a preliminary assessment of the effect of a single IVT administration of VEGF Trap-Eye on visual acuity
   Assessments for visual acuity are performed at each visit (Visit 1 - Visit 10).

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).
- On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
- Retinal Thickness at the center point ≥ 250 microns.
- Media clarity, pupillary dilation, and patient cooperation sufficient for adequate fundus photographs.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Visit 2 (Day 1).
- Macular edema due to causes other than diabetic macular edema. An eye should be considered ineligible: (1) if the macular edema is considered to be related to cataract extraction or (2) clinical exam and/or OCT suggests that vitreoretinal interface disease (e.g., a taut posterior hyaloid or epiretinal membrane) is the primary cause of the macular edema.
- An ocular condition is present such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g., foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).
- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, age-related macular degeneration, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, etc.).
- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase 1 study.

Contacts/Locations

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Maryland**

Baltimore, Maryland, United States, 21287

United States, North Carolina

Charlotte, North Carolina, United States, 28210

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Citations:

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ClinicalTrials.gov archive

History of Changes for Study: NCT00320814

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Latest version (submitted June 8, 2011) on ClinicalTrials.gov

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3	○	○	January 5, 2009	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Oversight, Contacts/Locations, Study Design and Sponsor/Collaborators

Version	A	B	Submitted Date	Changes
4	◉	◉	January 25, 2011	Study Status
5	○	○	June 8, 2011	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320814

Submitted Date: January 25, 2011 (v4)

Study Identification

Unique Protocol ID: VGFT-OD-0512

Brief Title: Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Official Title: An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema

Secondary IDs:

Study Status

Record Verification: January 2011

Overall Status: Completed

Study Start: April 2006

Primary Completion: August 2006 [Actual]

Study Completion: August 2007 [Actual]

First Submitted: April 28, 2006

First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	January 25, 2011
Last Update Posted:	January 26, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema.
Detailed Description:	This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 5 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1	Drug: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1

Outcome Measures

Primary Outcome Measures:

1. To assess the ocular and systemic safety and tolerability of a single intravitreal (IVT) injection of VEGF Trap-Eye in patients with diabetic macular edema (DME)
   Assessments for safety and tolerablity are performed at each visit (Visit 1 - Visit 10)

Secondary Outcome Measures:

2. To obtain a preliminary assessment of the effect of a single dose of VEGF Trap-Eye on central retinal thickness (CRT) at the center point as determined by optical coherence tomography (OCT)
   Assessments for CRT are performed at each visit (Visit 1 - Visit 10) by means of OCT.
3. To obtain a preliminary assessment of the effect of a single IVT administration of VEGF Trap-Eye on visual acuity
   Assessments for visual acuity are performed at each visit (Visit 1 - Visit 10).

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).
- On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
- Retinal Thickness at the center point ≥ 250 microns.
- Media clarity, pupillary dilation, and patient cooperation sufficient for adequate fundus photographs.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Visit 2 (Day 1).
- Macular edema due to causes other than diabetic macular edema. An eye should be considered ineligible: (1) if the macular edema is considered to be related to cataract extraction or (2) clinical exam and/or OCT suggests that vitreoretinal interface disease (e.g., a taut posterior hyaloid or epiretinal membrane) is the primary cause of the macular edema.
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Contacts/Locations

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Maryland**

Baltimore, Maryland, United States, 21287

United States, North Carolina

Charlotte, North Carolina, United States, 28210

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History of Changes for Study: NCT00320814

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Latest version (submitted June 8, 2011) on ClinicalTrials.gov

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Version	A	B	Submitted Date	Changes
4	○	○	January 25, 2011	Study Status
5	○	○	June 8, 2011	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320814

Submitted Date: January 5, 2009 (v3)

Study Identification

Unique Protocol ID: VGFT-OD-0512

Brief Title: Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Official Title: An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema

Secondary IDs:

Study Status

Record Verification: January 2009

Overall Status: Completed

Study Start: April 2006

Primary Completion: August 2006 [Actual]

Study Completion: August 2007 [Actual]

First Submitted: April 28, 2006

First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	January 5, 2009
Last Update Posted:	January 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema.
Detailed Description:	This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 5 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1	Drug: VEGF Trap-Eye single IVT injection of 4.0 mg of VEGF Trap-Eye into the study eye on Day 1

Outcome Measures

Primary Outcome Measures:

1. To assess the ocular and systemic safety and tolerability of a single intravitreal (IVT) injection of VEGF Trap-Eye in patients with diabetic macular edema (DME)
   Assessments for safety and tolerablity are performed at each visit (Visit 1 - Visit 10)

Secondary Outcome Measures:

2. To obtain a preliminary assessment of the effect of a single dose of VEGF Trap-Eye on central retinal thickness (CRT) at the center point as determined by optical coherence tomography (OCT)
   Assessments for CRT are performed at each visit (Visit 1 - Visit 10) by means of OCT.
3. To obtain a preliminary assessment of the effect of a single IVT administration of VEGF Trap-Eye on visual acuity
   Assessments for visual acuity are performed at each visit (Visit 1 - Visit 10).

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).
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- Media clarity, pupillary dilation, and patient cooperation sufficient for adequate fundus photographs.

Exclusion Criteria:

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Charlotte, North Carolina, United States, 28210

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00320814

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

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2	◉	◉	September 6, 2006	Recruitment Status, Study Status and Contacts/Locations
3	○	○	January 5, 2009	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Oversight, Contacts/Locations, Study Design and Sponsor/Collaborators

Version	A	B	Submitted Date	Changes
4	○	○	January 25, 2011	Study Status
5	○	○	June 8, 2011	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00320814

Submitted Date: September 6, 2006 (v2)

Study Identification

Unique Protocol ID: VGFT-OD-0512

Brief Title: Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Official Title: An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema

Secondary IDs:

Study Status

Record Verification: September 2006

Overall Status: Active, not recruiting

Study Start: April 2006

Primary Completion:

Study Completion:

First Submitted: April 28, 2006

First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	September 6, 2006
Last Update Posted:	September 8, 2006 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary:	To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema.
Detailed Description:	This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 5

Arms and Interventions

Intervention Details:

Drug: VEGF Trap

Outcome Measures

Primary Outcome Measures:

1. Safety and tolerability, Bioeffect

Secondary Outcome Measures:

2. The effect of VEGF Trap administration on: central retinal thickness, visual acuity and anti-VEGF Trap antibodies in the systemic circulation

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).

- On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
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- Macular edema due to causes other than diabetic macular edema. An eye should be considered ineligible: (1) if the macular edema is considered to be related to cataract extraction or (2) clinical exam and/or OCT suggests that vitreoretinal interface disease (e.g., a taut posterior hyaloid or epiretinal membrane) is the primary cause of the macular edema.
- An ocular condition is present such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g., foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).
- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, age-related macular degeneration, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, etc.).
- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase 1 study.

Contacts/Locations

Locations: **United States, Maryland**

Baltimore, Maryland, United States, 21287

United States, North Carolina

Charlotte, North Carolina, United States, 28210

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History of Changes for Study: NCT00320814

Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Latest version (submitted June 8, 2011) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
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- Click "Compare" to do the comparison and show the differences.
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- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	April 28, 2006	None (earliest Version on record)
2	○	○	September 6, 2006	Recruitment Status, Study Status and Contacts/Locations
3	○	○	January 5, 2009	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Oversight, Contacts/Locations, Study Design and Sponsor/Collaborators

Version	A	B	Submitted Date	Changes
4	○	○	January 25, 2011	Study Status
5	○	○	June 8, 2011	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00320814

Submitted Date: April 28, 2006 (v1)

Study Identification

Unique Protocol ID: VGFT-OD-0512

Brief Title: Phase 1 Study of VEGF Trap in Patients With Diabetic Macular Edema

Official Title: An Exploratory Study of the Safety, Tolerability and Biological Effect of a Single Intravitreal Administration of VEGF Trap in Patients With Diabetic Macular Edema

Secondary IDs:

Study Status

Record Verification: April 2006

Overall Status: Recruiting

Study Start: April 2006

Primary Completion:

Study Completion:

First Submitted: April 28, 2006

First Submitted that Met QC Criteria:	April 28, 2006
First Posted:	May 3, 2006 [Estimate]
Last Update Submitted that Met QC Criteria:	April 28, 2006
Last Update Posted:	May 3, 2006 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary:	To assess the ocular and systemic safety and tolerability of a single intravitreal injection of VEGF Trap in patients with diabetic macular edema.
Detailed Description:	This is an open label study. Initially, 5 patients with DME will receive an ITV injection of VEGF Trap into the study eye. Additional patients may be enrolled at the same or additional dose levels. Patients will be observed for six weeks following the injection for assessments of ocular and systemic safety.

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 5

Arms and Interventions

Intervention Details:

Drug: VEGF Trap

Outcome Measures

Primary Outcome Measures:

1. Safety and tolerability, Bioeffect

Secondary Outcome Measures:

2. The effect of VEGF Trap administration on: central retinal thickness, visual acuity and anti-VEGF Trap antibodies in the systemic circulation

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Diagnosis of diabetes mellitus (type 1 or type 2).
- Best corrected E-ETDRS visual acuity score of ≥ 24 letters (i.e., 20/320 or better) and ≤ 73 letters (i.e., 20/40 or worse).

- On clinical exam, definite retinal thickening due to diabetic macular edema involving the center of the macula.
- Retinal Thickness at the center point ≥ 250 microns.
- Media clarity, pupillary dilation, and patient cooperation sufficient for adequate fundus photographs.

Exclusion Criteria:

- History of any vitreous hemorrhage within 4 weeks prior to Visit 2 (Day 1).
- Macular edema due to causes other than diabetic macular edema. An eye should be considered ineligible: (1) if the macular edema is considered to be related to cataract extraction or (2) clinical exam and/or OCT suggests that vitreoretinal interface disease (e.g., a taut posterior hyaloid or epiretinal membrane) is the primary cause of the macular edema.
- An ocular condition is present such that, in the opinion of the investigator, visual acuity would not improve from resolution of macular edema (e.g., foveal atrophy, pigmentary changes, dense subfoveal hard exudates, nonretinal condition).
- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, age-related macular degeneration, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, etc.).
- Presence of any other condition or laboratory abnormality, which, in the opinion of the Investigator, would interfere with the assessment of disease status/progression or jeopardize the patient's appropriate participation in this Phase 1 study.

Contacts/Locations

Central Contact: Regeneron
Email: VEGF.Trap@regeneron.com

Locations: **United States, Maryland**

[Not yet recruiting]
Baltimore, Maryland, United States, 21287

United States, North Carolina

[Recruiting]

Charlotte, North Carolina, United States, 28210

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

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4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	◉	◉	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

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Study NCT00509795

Submitted Date: December 1, 2011 (v15)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2011

Overall Status: Completed

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Actual]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	December 1, 2011
Last Update Posted:	December 8, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Arms	Assigned Interventions
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.

15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

United States, Iowa

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Kentucky

Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

United States, Michigan

Ann Arbor, Michigan, United States, 48105

Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

Las Vegas, Nevada, United States, 89144

United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

Syracuse, New York, United States, 13224

United States, North Carolina

Asheville, North Carolina, United States, 28803

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43608

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsberg, Pennsylvania, United States, 15231

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Charleston, South Carolina, United States, 29414

Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

Corpus Cristi, Texas, United States, 78413

Dallas, Texas, United States, 75390

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Fairfax, Virginia, United States, 22031

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Silverdale, Washington, United States, 98383

United States, Wisconsin

Madison, Wisconsin, United States, 53715

Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Ottawa, Ontario, Canada, K1H8L6

Toronto, Ontario, Canada, M4N3M5

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

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15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: May 4, 2011 (v14)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2011

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	May 4, 2011
Last Update Posted:	May 6, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Arms	Assigned Interventions
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.

15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

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New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

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Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

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Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

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Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

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Wichita, Kansas, United States, 67214

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Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

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Baltimore, Maryland, United States, 21209

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Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

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Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

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Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

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Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

Syracuse, New York, United States, 13224

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Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

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Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43608

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsberg, Pennsylvania, United States, 15231

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

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Providence, Rhode Island, United States, 02903-4928

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Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

Corpus Cristi, Texas, United States, 78413

Dallas, Texas, United States, 75390

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78240

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Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Fairfax, Virginia, United States, 22031

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Silverdale, Washington, United States, 98383

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Madison, Wisconsin, United States, 58705

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Mississauga, Ontario, Canada, L4W 1W9

Ottawa, Ontario, Canada, K1H8L6

Toronto, Ontario, Canada, M4N3M5

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	◉	◉	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: April 18, 2011 (v13)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2011

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	April 18, 2011
Last Update Posted:	April 27, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Arms	Assigned Interventions
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
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2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
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Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

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Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

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Mountain View, California, United States, 94040

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Poway, California, United States, 92064

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Denver, Colorado, United States, 80230

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Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

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Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

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Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

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Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

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New Orleans, Louisiana, United States, 70115

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Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

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Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

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Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

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Minneapolis, Minnesota, United States, 55404

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Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

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Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

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Study Record Versions

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14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
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18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

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Study NCT00509795

Submitted Date: January 5, 2011 (v12)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: January 2011

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: December 2011 [Anticipated]

Study Completion: December 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	January 5, 2011
Last Update Posted:	January 10, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Arms	Assigned Interventions
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.

15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

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United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

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History of Changes for Study: NCT00509795

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18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

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Comparison Format: (•) Merged ( ) Side-by-Side

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Study NCT00509795

Submitted Date: December 1, 2009 (v11)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2009

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: December 2011 [Anticipated]

Study Completion: December 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	December 1, 2009
Last Update Posted:	December 2, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has

lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

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San Francisco, California, United States, 94107

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Ventura, California, United States, 93003

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Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

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Toronto, Ontario, Canada, M5C 2T2

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Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	◉	◉	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: September 12, 2009 (v10)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: September 2009

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: December 2011 [Anticipated]

Study Completion: December 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	September 12, 2009
Last Update Posted:	September 15, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has

lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
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2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
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Contacts/Locations

Study Officials: Avner Ingerman, MD
Study Director
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Stuart, Florida, United States, 34994

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Shreveport, Louisiana, United States, 71105

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Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

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Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

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St. Louis, Missouri, United States, 63110

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Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

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United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

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Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

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United States, North Carolina

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Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

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West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Charleston, South Carolina, United States, 29414

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Greenville, South Carolina, United States, 29605

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Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

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Ottawa, Ontario, Canada, K1H8L6

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Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	◉	◉	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: April 28, 2009 (v9)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2009

Overall Status: Recruiting

Study Start: August 2007

Primary Completion: December 2011 [Anticipated]

Study Completion: December 2011 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	April 28, 2009
Last Update Posted:	April 29, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2.0 mg dose at week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: 4	Drug: ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has

lost fewer than 15 letters on the ETDRS chart compared to baseline (i.e. prevention of moderate vision loss)
Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52
3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Telephone: 866-549-8439
Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Recruiting]
Birmingham, Alabama, United States, 35205

[Recruiting]
Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]
Phoenix, Arizona, United States, 85014

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

[Recruiting]
Tucson, Arizona, United States, 85710

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Recruiting]
Campbell, California, United States, 95008

[Recruiting]
Fullerton, California, United States, 92835

[Terminated]
Glendale, California, United States, 91203

[Recruiting]
Irvine, California, United States, 92697

[Recruiting]
La Jolla, California, United States, 92037

[Recruiting]

Loma Linda, California, United States, 92354

[Withdrawn]

Los Angeles, California, United States, 90033

[Recruiting]

Los Angeles, California, United States, 90048

[Recruiting]

Menlo Park, California, United States, 94025

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Palm Springs, California, United States, 92262

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Pasadena, California, United States, 91105

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Poway, California, United States, 92064

[Recruiting]

Sacramento, California, United States, 95819

[Active, not recruiting]

San Diego, California, United States, 92120

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San Francisco, California, United States, 94107

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Santa Ana, California, United States, 92705

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Torrance, California, United States, 90503

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Ventura, California, United States, 93003

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Westlake Village, California, United States, 91361

[Recruiting]

Yorba Linda, California, United States, 92887

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Aurora, Colorado, United States, 80045

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Denver, Colorado, United States, 80205

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United States, Connecticut

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New Haven, Connecticut, United States, 06510

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New London, Connecticut, United States, 06320

United States, Florida

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Altamonte Springs, Florida, United States, 32701

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Boynton Beach, Florida, United States, 33426

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Fort Myers, Florida, United States, 33907

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Ft. Lauderdale, Florida, United States, 33351

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Jacksonville, Florida, United States, 32224

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Miami, Florida, United States, 33136

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Palm Beach Gardens, Florida, United States, 33410

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Pensacola, Florida, United States, 32503

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Sarasota, Florida, United States

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Stuart, Florida, United States, 34994

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Augusta, Georgia, United States, 30909

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Honolulu, Hawaii, United States, 96813

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Indianapolis, Indiana, United States, 46202

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New Albany, Indiana, United States, 47150

United States, Iowa

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Iowa City, Iowa, United States, 52242-1091

United States, Kansas

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Wichita, Kansas, United States, 67214

United States, Kentucky

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Louisville, Kentucky, United States, 40202

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Bangor, Maine, United States, 04401

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Portland, Maine, United States, 04102

United States, Maryland

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Baltimore, Maryland, United States, 21209

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Chevy Chase, Maryland, United States, 20815

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Hagerstown, Maryland, United States, 21740

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Towson, Maryland, United States, 21204

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Boston, Massachusetts, United States, 02111

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Peabody, Massachusetts, United States, 01960

United States, Michigan

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Ann Arbor, Michigan, United States, 48105

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[Recruiting]
Fairfax, Virginia, United States, 22031

[Recruiting]
Richmond, Virginia, United States, 23221

United States, Washington

[Recruiting]

Seattle, Washington, United States, 98104

[Recruiting]

Silverdale, Washington, United States, 98383

United States, Wisconsin

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Madison, Wisconsin, United States, 53715

[Recruiting]

Madison, Wisconsin, United States, 58705

[Recruiting]

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Recruiting]

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

[Recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Recruiting]

Ottawa, Ontario, Canada, K1H8L6

[Recruiting]

Toronto, Ontario, Canada, M4N3M5

[Active, not recruiting]

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

[Recruiting]

Montreal, Quebec, Canada, H1T 2M4

[Recruiting]

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Recruiting]

Regina, Saskatchewan, Canada, S4T 1A5

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History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	◉	◉	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: March 3, 2009 (v8)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: March 2009

Overall Status: Recruiting

Study Start: August 2007

Primary Completion: October 2010 [Anticipated]

Study Completion: January 2012 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	March 3, 2009
Last Update Posted:	March 5, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 2	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 3	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab
Active Comparator: 4	Drug: Comparator 0.5 mg ranibizumab adm. every 4 wks (RQ4);

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline.
   Monthly

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.
   as dictated by protocol

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. CNV must be at least 50% of total lesion size.
5. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
6. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
7. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Prior treatment with anti-VEGF agents as follows:
    - Prior treatment with anti-VEGF therapy in the study eye is not allowed.
    - Prior treatment with anti-VEGF therapy in the fellow eye with an investigational agent (not FDA approved, e.g. bevacizumab) is allowed up to 3 months prior to first dose in the study, and such treatment will not be allowed during the study. Prior treatment with an FDA/Health Canada approved anti-VEGF therapy in the fellow eye is allowed.

- Prior systemic anti-VEGF therapy, investigational or FDA/Health Canada approved, is only allowed up to 3 months prior to first dose, and will not be allowed during the study

4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Telephone: 866-549-8439
Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Recruiting]

Birmingham, Alabama, United States, 35205

[Recruiting]

Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]

Phoenix, Arizona, United States, 85014

[Recruiting]

Phoenix, Arizona, United States, 85020

[Recruiting]

Tucson, Arizona, United States, 85704

[Recruiting]

Tucson, Arizona, United States, 85710

United States, California

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Campbell, California, United States, 95008

[Recruiting]

Fullerton, California, United States, 92835

[Terminated]

Glendale, California, United States, 91203

[Recruiting]

Irvine, California, United States, 92697

[Recruiting]

La Jolla, California, United States, 92037

[Recruiting]

Loma Linda, California, United States, 92354

[Withdrawn]

Los Angeles, California, United States, 90033

[Recruiting]

Los Angeles, California, United States, 90048

[Recruiting]

Menlo Park, California, United States, 94025

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Palm Springs, California, United States, 92262

[Recruiting]

Pasadena, California, United States, 91105

[Withdrawn]

Poway, California, United States, 92064

[Recruiting]

Sacramento, California, United States, 95819

[Active, not recruiting]

San Diego, California, United States, 92120

[Terminated]

San Francisco, California, United States, 94107

[Recruiting]

Santa Ana, California, United States, 92705

[Recruiting]

Torrance, California, United States, 90503

[Withdrawn]

Ventura, California, United States, 93003

[Recruiting]

Westlake Village, California, United States, 91361

[Recruiting]

Yorba Linda, California, United States, 92887

United States, Colorado

[Terminated]

Aurora, Colorado, United States, 80045

[Recruiting]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80230

United States, Connecticut

[Recruiting]

Bridgeport, Connecticut, United States, 06606

[Withdrawn]

Hamden, Connecticut, United States, 06518

[Active, not recruiting]

New Haven, Connecticut, United States, 06510

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33907

[Withdrawn]

Ft. Lauderdale, Florida, United States, 33351

[Recruiting]

Ft. Myers, Florida, United States, 33912

[Withdrawn]

Gainesville, Florida, United States, 32610

[Recruiting]

Jacksonville, Florida, United States, 32224

[Withdrawn]

Miami, Florida, United States, 33136

[Recruiting]

Miami, Florida, United States, 33143

[Terminated]

Mount Dora, Florida, United States, 32757

[Recruiting]

Orlando, Florida, United States, 32803

[Recruiting]

Orlando, Florida, United States, 32806

[Recruiting]

Oscala, Florida, United States, 34472

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Pensacola, Florida, United States, 32503

[Withdrawn]

Sarasota, Florida, United States

[Recruiting]

Stuart, Florida, United States, 34994

[Recruiting]

Tampa, Florida, United States, 33612

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Aiea, Hawaii, United States, 96701

[Withdrawn]

Honolulu, Hawaii, United States, 96813

United States, Illinois

[Recruiting]

Oak Brook, Illinois, United States, 60523

United States, Indiana

[Recruiting]

Fort Wayne, Indiana, United States, 46804

[Recruiting]

Indianapolis, Indiana, United States, 46202

[Terminated]

Indianapolis, Indiana, United States, 46260

[Recruiting]

Indianapolis, Indiana, United States, 46280

[Recruiting]

New Albany, Indiana, United States, 47150

United States, Iowa

[Recruiting]

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

[Recruiting]

Wichita, Kansas, United States, 67214

United States, Kentucky

[Recruiting]

Louisville, Kentucky, United States, 40202

[Recruiting]

Louisville, Kentucky, United States, 40207

[Terminated]

Paducah, Kentucky, United States, 42001

United States, Louisiana

[Recruiting]

New Orleans, Louisiana, United States, 70115

[Recruiting]

New Orleans, Louisiana, United States, 70121

[Terminated]

Shreveport, Louisiana, United States, 71105

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

[Recruiting]

Portland, Maine, United States, 04102

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21209

[Recruiting]

Baltimore, Maryland, United States, 21287

[Recruiting]

Chevy Chase, Maryland, United States, 20815

[Recruiting]

Hagerstown, Maryland, United States, 21740

[Recruiting]

Towson, Maryland, United States, 21204

United States, Massachusetts

[Withdrawn]

Boston, Massachusetts, United States, 02111

[Recruiting]

Boston, Massachusetts, United States, 02114

[Recruiting]

Boston, Massachusetts, United States, 02215

[Withdrawn]

Boston, Massachusetts, United States

[Recruiting]

Peabody, Massachusetts, United States, 01960

United States, Michigan

[Recruiting]

Ann Arbor, Michigan, United States, 48105

[Recruiting]

Battle Creek, Michigan, United States, 49015

[Active, not recruiting]

Detroit, Michigan, United States, 48202

[Recruiting]

Grand Rapids, Michigan, United States, 49525

[Recruiting]

Jackson, Michigan, United States, 49201

[Recruiting]

Royal Oak, Michigan, United States, 48073

[Recruiting]

Southfield, Michigan, United States, 48034

[Withdrawn]

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

[Withdrawn]

Edina, Minnesota, United States, 55435

[Recruiting]

Minneapolis, Minnesota, United States, 55404

[Recruiting]

Rochester, Minnesota, United States, 55905

United States, Missouri

[Recruiting]

Florissant, Missouri, United States, 63031

[Recruiting]

Kansas City, Missouri, United States, 64108

[Withdrawn]

Kansas City, Missouri, United States, 64111

[Recruiting]

Springfield, Missouri, United States, 65804

[Recruiting]

St. Louis, Missouri, United States, 63110

United States, Montana

[Recruiting]

Missoula, Montana, United States, 59801

United States, Nebraska

[Recruiting]
Lincoln, Nebraska, United States, 68506

[Withdrawn]
Omaha, Nebraska, United States, 68131

United States, Nevada

[Recruiting]
Las Vegas, Nevada, United States, 89144

United States, New Jersey

[Recruiting]
Lawrenceville, New Jersey, United States, 08648

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New Brunswick, New Jersey, United States, 08901

[Recruiting]
Northfield, New Jersey, United States, 08225

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Teaneck, New Jersey, United States, 07666

[Recruiting]
Toms River, New Jersey, United States, 08753

United States, New Mexico

[Recruiting]
Albuquerque, New Mexico, United States, 87106

United States, New York

[Recruiting]
Albany, New York, United States, 12206

[Recruiting]

Brooklyn, New York, United States, 11223

[Recruiting]

Lynbrook, New York, United States, 11563

[Recruiting]

New York, New York, United States, 10003

[Recruiting]

New York, New York, United States, 10021

[Recruiting]

New York, New York, United States, 10032

[Terminated]

Poughkeepsie, New York, United States, 12601

[Recruiting]

Rochester, New York, United States, 14620

[Recruiting]

Rochester, New York, United States, 14642

[Recruiting]

Slingerlands, New York, United States, 12159

[Recruiting]

Syracuse, New York, United States, 13224

United States, North Carolina

[Recruiting]

Asheville, North Carolina, United States, 28803

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

[Terminated]

Southern Pines, North Carolina, United States, 28387

[Recruiting]

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

[Withdrawn]

Cincinnati, Ohio, United States, 45202

[Recruiting]

Cincinnati, Ohio, United States, 45242

[Terminated]

Columbus, Ohio, United States, 43215

[Terminated]

Toledo, Ohio, United States, 43608

United States, Oklahoma

[Recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]

Ashland, Oregon, United States, 97520

[Recruiting]

Portland, Oregon, United States, 97210

[Recruiting]

Portland, Oregon, United States, 97227

[Recruiting]

Salem, Oregon, United States, 97302

United States, Pennsylvania

[Recruiting]

Kingston, Pennsylvania, United States, 18704

[Active, not recruiting]

Philadelphia, Pennsylvania, United States, 19104

[Recruiting]

Philadelphia, Pennsylvania, United States, 19107

[Recruiting]

Philadelphia, Pennsylvania, United States, 19124

[Recruiting]

Pittsberg, Pennsylvania, United States, 15231

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15212

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

[Recruiting]

West Mifflin, Pennsylvania, United States, 15122

[Withdrawn]

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

[Recruiting]

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

[Recruiting]

Charleston, South Carolina, United States, 29414

[Recruiting]

Columbia, South Carolina, United States, 29223

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Terminated]

Memphis, Tennessee, United States, 38119

[Terminated]

Memphis, Tennessee, United States, 38120

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Active, not recruiting]

Corpus Cristi, Texas, United States, 78413

[Recruiting]

Dallas, Texas, United States, 75390

[Terminated]

DeSoto, Texas, United States, 75115

[Recruiting]

Ft. Worth, Texas, United States, 76102

[Recruiting]

Ft. Worth, Texas, United States, 76104

[Withdrawn]

Galveston, Texas, United States, 77555

[Recruiting]

Houston, Texas, United States, 77030

[Withdrawn]

Houston, Texas, United States, 77030

[Terminated]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

Odessa, Texas, United States, 79761

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

[Recruiting]

Salt Lake City, Utah, United States, 84132

United States, Vermont

[Recruiting]

Burlington, Vermont, United States, 05401

United States, Virginia

[Recruiting]

Charlottesville, Virginia, United States, 22908

[Recruiting]

Fairfax, Virginia, United States, 22031

[Recruiting]

Richmond, Virginia, United States, 23221

United States, Washington

[Recruiting]

Seattle, Washington, United States, 98104

[Recruiting]

Silverdale, Washington, United States, 98383

United States, Wisconsin

[Recruiting]

Madison, Wisconsin, United States, 53715

[Recruiting]

Madison, Wisconsin, United States, 58705

[Recruiting]

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Recruiting]

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

[Recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Recruiting]

Ottawa, Ontario, Canada, K1H8L6

[Recruiting]

Toronto, Ontario, Canada, M4N3M5

[Active, not recruiting]

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

[Recruiting]

Montreal, Quebec, Canada, H1T 2M4

[Recruiting]

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Recruiting]

Regina, Saskatchewan, Canada, S4T 1A5

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

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Version	A	B	Submitted Date	Changes
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7	◉	◉	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

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Study NCT00509795

Submitted Date: January 22, 2009 (v7)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: January 2009

Overall Status: Recruiting

Study Start: August 2007

Primary Completion: October 2010 [Anticipated]

Study Completion: January 2012 [Anticipated]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	January 22, 2009
Last Update Posted:	January 26, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 2	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab

Arms	Assigned Interventions
Experimental: 3	Drug: VEGF Trap-Eye VGFT-OD-0605 is a double-masked, randomized, Phase III study. Subjects will be rand. assigned in a 1:1:1:1 ratio to 1 of 4 dosing regimens:1)2mg VEGF Trap-Eye adm. every 4 wks (2Q4), 2) 0.5mg VEGF Trap-Eye adm. every 4 wks (0.5Q4), 3) 2mg VEGF Trap-Eye adm. every 8 wks (2Q8), and 4) 0.5mg ranibizumab adm. every 4 wks (RQ4); subj. assigned to (2Q8) will receive the 2mg injection every 4 wks to wk 8 & then a sham inject at interim 4-wk visits (when study drug is not to be adm) during the first 52 wks of the study. VEGF Trap-Eye will be supplied in sealed 3mL single use vials each with a "withdrawable" vol. of approx. 0.5 mL at a concentration of 10mg/mL or 40 mg/mL.VEGF Trap-Eye will be withdrawn using aseptic technique through an 18 "gauge" needle attached to a 1 mL syringe. The syringe needle will then be removed and replaced with a 30 gauge needle to be used for the ITV inject. The inject. vol. will be 50µL (0.05 mL) for the 0.5mg & 2mg doses of VEGF Trap-Eye and 0.5 mg ranibizumab
Active Comparator: 4	Drug: Comparator 0.5 mg ranibizumab adm. every 4 wks (RQ4);

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline.
   Monthly

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.
   as dictated by protocol

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. CNV must be at least 50% of total lesion size.
5. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
6. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
7. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Prior treatment with anti-VEGF agents as follows:
    - Prior treatment with anti-VEGF therapy in the study eye is not allowed.
    - Prior treatment with anti-VEGF therapy in the fellow eye with an investigational agent (not FDA approved, e.g. bevacizumab) is allowed up to 3 months prior to first dose in the study, and such treatment will not be allowed during the study. Prior treatment with an FDA/Health Canada approved anti-VEGF therapy in the fellow eye is allowed.

- Prior systemic anti-VEGF therapy, investigational or FDA/Health Canada approved, is only allowed up to 3 months prior to first dose, and will not be allowed during the study

4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Telephone: 866-549-8439
Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Recruiting]

Birmingham, Alabama, United States, 35205

[Recruiting]

Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]

Phoenix, Arizona, United States, 85014

[Recruiting]

Phoenix, Arizona, United States, 85020

[Recruiting]

Tucson, Arizona, United States, 85704

[Recruiting]

Tucson, Arizona, United States, 85710

United States, California

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Campbell, California, United States, 95008

[Recruiting]

Fullerton, California, United States, 92835

[Terminated]

Glendale, California, United States, 91203

[Recruiting]

Irvine, California, United States, 92697

[Recruiting]

La Jolla, California, United States, 92037

[Recruiting]

Loma Linda, California, United States, 92354

[Withdrawn]

Los Angeles, California, United States, 90033

[Recruiting]

Los Angeles, California, United States, 90048

[Recruiting]

Menlo Park, California, United States, 94025

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Palm Springs, California, United States, 92262

[Recruiting]

Pasadena, California, United States, 91105

[Withdrawn]

Poway, California, United States, 92064

[Recruiting]

Sacramento, California, United States, 95819

[Active, not recruiting]

San Diego, California, United States, 92120

[Terminated]

San Francisco, California, United States, 94107

[Recruiting]

Santa Ana, California, United States, 92705

[Active, not recruiting]

Torrance, California, United States, 90503

[Withdrawn]

Ventura, California, United States, 93003

[Recruiting]

Westlake Village, California, United States, 91361

[Recruiting]

Yorba Linda, California, United States, 92887

United States, Colorado

[Terminated]

Aurora, Colorado, United States, 80045

[Recruiting]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80205

[Withdrawn]

Denver, Colorado, United States, 80230

United States, Connecticut

[Recruiting]

Bridgeport, Connecticut, United States, 06606

[Withdrawn]

Hamden, Connecticut, United States, 06518

[Active, not recruiting]

New Haven, Connecticut, United States, 06510

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33907

[Withdrawn]

Ft. Lauderdale, Florida, United States, 33351

[Recruiting]

Ft. Myers, Florida, United States, 33912

[Withdrawn]

Gainesville, Florida, United States, 32610

[Recruiting]

Jacksonville, Florida, United States, 32224

[Withdrawn]

Miami, Florida, United States, 33136

[Recruiting]

Miami, Florida, United States, 33143

[Recruiting]

Mount Dora, Florida, United States, 32757

[Recruiting]

Orlando, Florida, United States, 32803

[Recruiting]

Orlando, Florida, United States, 32806

[Recruiting]

Oscala, Florida, United States, 34472

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Pensacola, Florida, United States, 32503

[Withdrawn]

Sarasota, Florida, United States

[Recruiting]

Stuart, Florida, United States, 34994

[Recruiting]

Tampa, Florida, United States, 33612

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Aiea, Hawaii, United States, 96701

[Withdrawn]

Honolulu, Hawaii, United States, 96813

United States, Illinois

[Recruiting]

Oak Brook, Illinois, United States, 60523

United States, Indiana

[Recruiting]

Fort Wayne, Indiana, United States, 46804

[Recruiting]

Indianapolis, Indiana, United States, 46202

[Terminated]

Indianapolis, Indiana, United States, 46260

[Recruiting]

Indianapolis, Indiana, United States, 46280

[Recruiting]

New Albany, Indiana, United States, 47150

United States, Iowa

[Recruiting]

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

[Recruiting]

Wichita, Kansas, United States, 67214

United States, Kentucky

[Recruiting]

Louisville, Kentucky, United States, 40202

[Recruiting]

Louisville, Kentucky, United States, 40207

[Terminated]

Paducah, Kentucky, United States, 42001

United States, Louisiana

[Recruiting]

New Orleans, Louisiana, United States, 70115

[Recruiting]

New Orleans, Louisiana, United States, 70121

[Terminated]

Shreveport, Louisiana, United States, 71105

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

[Recruiting]

Portland, Maine, United States, 04102

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21209

[Recruiting]

Baltimore, Maryland, United States, 21287

[Recruiting]

Chevy Chase, Maryland, United States, 20815

[Recruiting]

Hagerstown, Maryland, United States, 21740

[Recruiting]

Towson, Maryland, United States, 21204

United States, Massachusetts

[Withdrawn]

Boston, Massachusetts, United States, 02111

[Recruiting]

Boston, Massachusetts, United States, 02114

[Recruiting]

Boston, Massachusetts, United States, 02215

[Withdrawn]

Boston, Massachusetts, United States

[Recruiting]

Peabody, Massachusetts, United States, 01960

United States, Michigan

[Recruiting]

Ann Arbor, Michigan, United States, 48105

[Recruiting]

Battle Creek, Michigan, United States, 49015

[Active, not recruiting]

Detroit, Michigan, United States, 48202

[Recruiting]

Grand Rapids, Michigan, United States, 49525

[Recruiting]

Jackson, Michigan, United States, 49201

[Recruiting]

Royal Oak, Michigan, United States, 48073

[Recruiting]

Southfield, Michigan, United States, 48034

[Withdrawn]

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

[Withdrawn]

Edina, Minnesota, United States, 55435

[Recruiting]

Minneapolis, Minnesota, United States, 55404

[Recruiting]

Rochester, Minnesota, United States, 55905

United States, Missouri

[Recruiting]

Florissant, Missouri, United States, 63031

[Recruiting]

Kansas City, Missouri, United States, 64108

[Withdrawn]

Kansas City, Missouri, United States, 64111

[Recruiting]

Springfield, Missouri, United States, 65804

[Recruiting]

St. Louis, Missouri, United States, 63110

United States, Montana

[Recruiting]

Missoula, Montana, United States, 59801

United States, Nebraska

[Recruiting]
Lincoln, Nebraska, United States, 68506

[Withdrawn]
Omaha, Nebraska, United States, 68131

United States, Nevada

[Recruiting]
Las Vegas, Nevada, United States, 89144

United States, New Jersey

[Recruiting]
Lawrenceville, New Jersey, United States, 08648

[Terminated]
New Brunswick, New Jersey, United States, 08901

[Recruiting]
Northfield, New Jersey, United States, 08225

[Withdrawn]
Teaneck, New Jersey, United States, 07666

[Recruiting]
Toms River, New Jersey, United States, 08753

United States, New Mexico

[Recruiting]
Albuquerque, New Mexico, United States, 87106

United States, New York

[Recruiting]
Albany, New York, United States, 12206

[Recruiting]

Brooklyn, New York, United States, 11223

[Recruiting]

Lynbrook, New York, United States, 11563

[Recruiting]

New York, New York, United States, 10003

[Recruiting]

New York, New York, United States, 10021

[Recruiting]

New York, New York, United States, 10032

[Terminated]

Poughkeepsie, New York, United States, 12601

[Recruiting]

Rochester, New York, United States, 14620

[Recruiting]

Rochester, New York, United States, 14642

[Recruiting]

Slingerlands, New York, United States, 12159

[Recruiting]

Syracuse, New York, United States, 13224

United States, North Carolina

[Recruiting]

Asheville, North Carolina, United States, 28803

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

[Terminated]

Southern Pines, North Carolina, United States, 28387

[Recruiting]

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

[Withdrawn]

Cincinnati, Ohio, United States, 45202

[Recruiting]

Cincinnati, Ohio, United States, 45242

[Terminated]

Columbus, Ohio, United States, 43215

[Recruiting]

Toledo, Ohio, United States, 43608

United States, Oklahoma

[Recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Recruiting]

Ashland, Oregon, United States, 97520

[Recruiting]

Portland, Oregon, United States, 97210

[Recruiting]

Portland, Oregon, United States, 97227

[Recruiting]

Salem, Oregon, United States, 97302

United States, Pennsylvania

[Recruiting]

Kingston, Pennsylvania, United States, 18704

[Active, not recruiting]

Philadelphia, Pennsylvania, United States, 19104

[Recruiting]

Philadelphia, Pennsylvania, United States, 19107

[Recruiting]

Philadelphia, Pennsylvania, United States, 19124

[Recruiting]

Pittsberg, Pennsylvania, United States, 15231

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15212

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

[Recruiting]

West Mifflin, Pennsylvania, United States, 15122

[Withdrawn]

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

[Recruiting]

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

[Recruiting]

Charleston, South Carolina, United States, 29414

[Recruiting]

Columbia, South Carolina, United States, 29223

[Recruiting]

Greenville, South Carolina, United States, 29605

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Memphis, Tennessee, United States, 38119

[Terminated]

Memphis, Tennessee, United States, 38120

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Active, not recruiting]

Corpus Cristi, Texas, United States, 78413

[Recruiting]

Dallas, Texas, United States, 75390

[Terminated]

DeSoto, Texas, United States, 75115

[Recruiting]

Ft. Worth, Texas, United States, 76102

[Recruiting]

Ft. Worth, Texas, United States, 76104

[Withdrawn]

Galveston, Texas, United States, 77555

[Recruiting]

Houston, Texas, United States, 77030

[Withdrawn]

Houston, Texas, United States, 77030

[Terminated]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

Odessa, Texas, United States, 79761

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

[Recruiting]

Salt Lake City, Utah, United States, 84132

United States, Vermont

[Recruiting]

Burlington, Vermont, United States, 05401

United States, Virginia

[Recruiting]

Charlottesville, Virginia, United States, 22908

[Recruiting]

Fairfax, Virginia, United States, 22031

[Recruiting]

Richmond, Virginia, United States, 23221

United States, Washington

[Recruiting]

Seattle, Washington, United States, 98104

[Recruiting]

Silverdale, Washington, United States, 98383

United States, Wisconsin

[Recruiting]

Madison, Wisconsin, United States, 53715

[Recruiting]

Madison, Wisconsin, United States, 58705

[Recruiting]

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Recruiting]

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

[Recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Recruiting]

Ottawa, Ontario, Canada, K1H8L6

[Active, not recruiting]
Toronto, Ontario, Canada, M4N3M5

[Active, not recruiting]
Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

[Recruiting]
Montreal, Quebec, Canada, H1T 2M4

[Recruiting]
Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	◉	◉	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
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11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
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17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: June 26, 2008 (v6)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: June 2008

Overall Status: Recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	June 26, 2008
Last Update Posted:	June 30, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Biological: VEGF Trap-Eye
Experimental: 2	Biological: VEGF Trap-Eye
Experimental: 3	Biological: VEGF Trap-Eye
Active Comparator: 4	Drug: Comparator

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline.

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.

3. Active primary subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. CNV must be at least 50% of total lesion size.
5. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
6. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
7. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Prior treatment with anti-VEGF agents as follows:
    - Prior treatment with anti-VEGF therapy in the study eye is not allowed.
    - Prior treatment with anti-VEGF therapy in the fellow eye with an investigational agent (not FDA approved, e.g. bevacizumab) is allowed up to 3 months prior to first dose in the study, and such treatment will not be allowed during the study. Prior treatment with an FDA/Health Canada approved anti-VEGF therapy in the fellow eye is allowed.
    - Prior systemic anti-VEGF therapy, investigational or FDA/Health Canada approved, is only allowed up to 3 months prior to first dose, and will not be allowed during the study
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.

10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Telephone: 866-549-8439
Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Recruiting]
Birmingham, Alabama, United States, 35205

[Recruiting]
Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]
Phoenix, Arizona, United States, 85014

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]

Tucson, Arizona, United States, 85704

[Recruiting]

Tucson, Arizona, United States, 85710

United States, California

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Campbell, California, United States, 95008

[Recruiting]

Fullerton, California, United States, 92835

[Not yet recruiting]

Glendale, California, United States, 91203

[Recruiting]

Irvine, California, United States, 92697

[Recruiting]

La Jolla, California, United States, 92037

[Recruiting]

Loma Linda, California, United States, 92354

[Not yet recruiting]

Los Angeles, California, United States, 90033

[Not yet recruiting]

Los Angeles, California, United States, 90048

[Recruiting]

Menlo Park, California, United States, 94025

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Oakland, California, United States, 94609

[Recruiting]

Orange, California, United States, 92868

[Recruiting]

Palm Springs, California, United States, 92262

[Recruiting]

Pasadena, California, United States, 91105

[Not yet recruiting]

Poway, California, United States, 92064

[Recruiting]

Sacramento, California, United States, 95819

[Not yet recruiting]

San Diego, California, United States, 92120

[Recruiting]

San Francisco, California, United States, 94107

[Recruiting]

Santa Ana, California, United States, 92705

[Not yet recruiting]

Ventura, California, United States, 93003

[Recruiting]

Westlake Village, California, United States, 91361

[Not yet recruiting]

Yorba Linda, California, United States, 92887

United States, Colorado

[Recruiting]

Aurora, Colorado, United States, 80045

[Recruiting]

Denver, Colorado, United States, 80205

United States, Connecticut

[Recruiting]

Bridgeport, Connecticut, United States, 06606

[Not yet recruiting]

New Haven, Connecticut, United States, 06510

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Altamonte Springs, Florida, United States, 32701

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Myers, Florida, United States, 33907

[Not yet recruiting]

Ft. Lauderdale, Florida, United States, 33351

[Recruiting]

Ft. Myers, Florida, United States, 33912

[Not yet recruiting]

Gainesville, Florida, United States, 32610

[Recruiting]

Jacksonville, Florida, United States, 32224

[Not yet recruiting]

Miami, Florida, United States, 33136

[Not yet recruiting]

Miami, Florida, United States, 33143

[Not yet recruiting]

Mount Dora, Florida, United States, 32757

[Recruiting]

Orlando, Florida, United States, 32803

[Recruiting]

Orlando, Florida, United States, 32806

[Recruiting]

Oscala, Florida, United States, 34472

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Pensacola, Florida, United States, 32503

[Recruiting]

Stuart, Florida, United States, 34994

[Recruiting]

Tampa, Florida, United States, 33612

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Aiea, Hawaii, United States, 96701

United States, Illinois

[Suspended]

Chicago, Illinois, United States, 60637

[Recruiting]

Glenview, Illinois, United States, 90026

[Recruiting]

Oak Brook, Illinois, United States, 60523

United States, Indiana

[Recruiting]
Fort Wayne, Indiana, United States, 46804

[Recruiting]
Indianapolis, Indiana, United States, 46202

[Recruiting]
Indianapolis, Indiana, United States, 46260

[Recruiting]
Indianapolis, Indiana, United States, 46280

[Recruiting]
New Albany, Indiana, United States, 47150

United States, Iowa

[Recruiting]
Iowa City, Iowa, United States, 52242-1091

United States, Kansas

[Recruiting]
Wichita, Kansas, United States, 67214

United States, Kentucky

[Recruiting]
Louisville, Kentucky, United States, 40202

[Recruiting]
Louisville, Kentucky, United States, 40207

[Recruiting]
Paducah, Kentucky, United States, 42001

United States, Louisiana

[Recruiting]
New Orleans, Louisiana, United States, 70115

[Recruiting]

New Orleans, Louisiana, United States, 70121

[Recruiting]

Shreveport, Louisiana, United States, 71105

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

[Recruiting]

Portland, Maine, United States, 04102

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21209

[Recruiting]

Baltimore, Maryland, United States, 21287

[Recruiting]

Chevy Chase, Maryland, United States, 20815

[Recruiting]

Hagerstown, Maryland, United States, 21740

[Recruiting]

Towson, Maryland, United States, 21204

United States, Massachusetts

[Not yet recruiting]

Boston, Massachusetts, United States, 02111

[Recruiting]

Boston, Massachusetts, United States, 02114

[Not yet recruiting]

Boston, Massachusetts, United States, 02215

[Recruiting]

Peabody, Massachusetts, United States, 01960

United States, Michigan

[Recruiting]
Ann Arbor, Michigan, United States, 48105

[Recruiting]
Battle Creek, Michigan, United States, 49015

[Not yet recruiting]
Detroit, Michigan, United States, 48202

[Recruiting]
Grand Rapids, Michigan, United States, 49525

[Recruiting]
Jackson, Michigan, United States, 49201

[Recruiting]
Royal Oak, Michigan, United States, 48073

[Recruiting]
Southfield, Michigan, United States, 48034

United States, Minnesota

[Recruiting]
Minneapolis, Minnesota, United States, 55404

[Recruiting]
Rochester, Minnesota, United States, 55905

United States, Missouri

[Recruiting]
Florissant, Missouri, United States, 63031

[Recruiting]
Kansas City, Missouri, United States, 64108

[Recruiting]
Springfield, Missouri, United States, 65804

[Recruiting]

St. Louis, Missouri, United States, 63110

United States, Montana

[Recruiting]

Missoula, Montana, United States, 59801

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, Nevada

[Recruiting]

Las Vegas, Nevada, United States, 89144

United States, New Jersey

[Recruiting]

Lawrenceville, New Jersey, United States, 08648

[Recruiting]

New Brunswick, New Jersey, United States, 08901

[Recruiting]

Northfield, New Jersey, United States, 08225

[Recruiting]

Toms River, New Jersey, United States, 08753

United States, New Mexico

[Recruiting]

Albuquerque, New Mexico, United States, 87106

United States, New York

[Recruiting]

Albany, New York, United States, 12159

[Recruiting]

Albany, New York, United States, 12206

[Recruiting]

Brooklyn, New York, United States, 11223

[Recruiting]

Lynbrook, New York, United States, 11563

[Recruiting]

New York, New York, United States, 10003

[Recruiting]

New York, New York, United States, 10021

[Recruiting]

New York, New York, United States, 10032

[Recruiting]

Poughkeepsie, New York, United States, 12601

[Recruiting]

Rochester, New York, United States, 14620

[Recruiting]

Rochester, New York, United States, 14642

[Recruiting]

Slingerlands, New York, United States, 12159

United States, North Carolina

[Recruiting]

Asheville, North Carolina, United States, 28803

[Recruiting]

Charlotte, North Carolina, United States, 28210

[Recruiting]

Raleigh, North Carolina, United States, 27607

[Recruiting]

Southern Pines, North Carolina, United States, 28387

[Recruiting]

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

[Not yet recruiting]

Cincinnati, Ohio, United States, 45202

[Recruiting]

Cincinnati, Ohio, United States, 45242

[Recruiting]

Columbus, Ohio, United States, 43215

[Recruiting]

Toledo, Ohio, United States, 43608

United States, Oklahoma

[Recruiting]

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

[Not yet recruiting]

Ashland, Oregon, United States, 97520

[Recruiting]

Portland, Oregon, United States, 97210

[Recruiting]

Portland, Oregon, United States, 97227

[Recruiting]

Salem, Oregon, United States, 97302

United States, Pennsylvania

[Recruiting]

Kingston, Pennsylvania, United States, 18704

[Not yet recruiting]

Philadelphia, Pennsylvania, United States, 19104

[Recruiting]

Philadelphia, Pennsylvania, United States, 19107

[Not yet recruiting]

Philadelphia, Pennsylvania, United States, 19124

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15212

[Recruiting]

Pittsburgh, Pennsylvania, United States, 15213

[Not yet recruiting]

Pittsburgh, Pennsylvania, United States, 15219

[Recruiting]

West Mifflin, Pennsylvania, United States, 15122

United States, Rhode Island

[Recruiting]

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

[Not yet recruiting]

Charleston, South Carolina, United States, 29414

[Recruiting]

Columbia, South Carolina, United States, 29223

[Recruiting]

Greenville, South Carolina, United States, 29605

[Not yet recruiting]

Mt. Pleasant, South Carolina, United States, 29464

[Recruiting]

West Columbia, South Carolina, United States, 29169

United States, South Dakota

[Recruiting]

Rapid City, South Dakota, United States, 57701

United States, Tennessee

[Recruiting]

Memphis, Tennessee, United States, 38119

[Terminated]

Memphis, Tennessee, United States, 38120

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Austin, Texas, United States, 78705

[Not yet recruiting]

Corpus Christi, Texas, United States, 78413

[Not yet recruiting]

Dallas, Texas, United States, 75390

[Recruiting]

DeSoto, Texas, United States, 75115

[Recruiting]

Ft. Worth, Texas, United States, 76102

[Recruiting]

Ft. Worth, Texas, United States, 76104

[Not yet recruiting]

Galveston, Texas, United States, 77555

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

Odessa, Texas, United States, 79761

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

[Recruiting]

Salt Lake City, Utah, United States, 84132

United States, Vermont

[Recruiting]

Burlington, Vermont, United States, 05401

United States, Virginia

[Recruiting]

Charlottesville, Virginia, United States, 22908

[Recruiting]

Fairfax, Virginia, United States, 22031

[Recruiting]

Richmond, Virginia, United States, 23221

United States, Washington

[Recruiting]

Seattle, Washington, United States, 98104

[Recruiting]

Silverdale, Washington, United States, 98383

United States, Wisconsin

[Recruiting]

Madison, Wisconsin, United States, 53715

[Recruiting]

Madison, Wisconsin, United States, 58705

[Recruiting]

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Recruiting]

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

[Not yet recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Not yet recruiting]

Ottawa, Ontario, Canada, K1H8L6

[Not yet recruiting]

Toronto, Ontario, Canada, M4N3M5

[Not yet recruiting]

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

[Recruiting]
Montreal, Quebec, Canada, H1T 2M4

[Recruiting]
Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	◉	◉	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: March 13, 2008 (v5)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: March 2008

Overall Status: Recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	March 13, 2008
Last Update Posted:	March 17, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap-Eye

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. CNV must be at least 50% of total lesion size.
5. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
6. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.

7. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Prior treatment with anti-VEGF agents as follows:
    - Prior treatment with anti-VEGF therapy in the study eye is not allowed.
    - Prior treatment with anti-VEGF therapy in the fellow eye with an investigational agent (not FDA approved, e.g. bevacizumab) is allowed up to 3 months prior to first dose in the study, and such treatment will not be allowed during the study. Prior treatment with an FDA/Health Canada approved anti-VEGF therapy in the fellow eye is allowed.
    - Prior systemic anti-VEGF therapy, investigational or FDA/Health Canada approved, is only allowed up to 3 months prior to first dose, and will not be allowed during the study
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.

14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Telephone: 866-549-8439
Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Not yet recruiting]
Birmingham, Alabama, United States, 35205

[Not yet recruiting]
Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]
Phoenix, Arizona, United States, 85014

[Recruiting]
Phoenix, Arizona, United States, 85020

[Recruiting]
Tucson, Arizona, United States, 85704

[Not yet recruiting]
Tucson, Arizona, United States, 85710

[Not yet recruiting]
Tucson, Arizona, United States, 85711

United States, California

[Recruiting]
Beverly Hills, California, United States, 90211

[Not yet recruiting]
Fullerton, California, United States, 92835

[Not yet recruiting]
Glendale, California, United States, 91203

[Not yet recruiting]
Irvine, California, United States, 92697

[Not yet recruiting]
La Jolla, California, United States, 92037

[Recruiting]
Loma Linda, California, United States, 92354

[Not yet recruiting]
Los Angeles, California, United States, 90033

[Not yet recruiting]
Los Angeles, California, United States, 90048

[Not yet recruiting]
Menlo Park, California, United States, 94025

[Recruiting]
Mountain View, California, United States, 94040

[Recruiting]
Oakland, California, United States, 94609

[Recruiting]
Palm Springs, California, United States, 92262

[Recruiting]
Pasadena, California, United States, 91105

[Not yet recruiting]
Poway, California, United States, 92064

[Not yet recruiting]
Sacramento, California, United States, 95819

[Not yet recruiting]
San Diego, California, United States, 92120

[Recruiting]
San Francisco, California, United States, 94107

[Not yet recruiting]
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Hagerstown, Maryland, United States, 21740

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Towson, Maryland, United States, 21204

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Boston, Massachusetts, United States, 02111

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Boston, Massachusetts, United States, 02215

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Peabody, Massachusetts, United States, 01960

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East Lansing, Michigan, United States, 48823

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Grand Blanc, Michigan, United States, 48439

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Southfield, Michigan, United States, 48034

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West Bloomfield, Michigan, United States, 48322

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Fargo, North Dakota, United States, 58103

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Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

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DeSoto, Texas, United States, 75115

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Salt Lake City, Utah, United States, 84107

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Burlington, Vermont, United States, 05401

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Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

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Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Not yet recruiting]
Vancouver, British Columbia, Canada, V5Z 3N9

[Not yet recruiting]
Victoria, British Columbia, Canada, V8X 5G6

Canada, Nova Scotia

[Not yet recruiting]

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Not yet recruiting]
London, Ontario, Canada, N6A 4G5

[Not yet recruiting]
Mississauga, Ontario, Canada, L4W 1W9

[Not yet recruiting]
Toronto, Ontario, Canada, M5C 2T2

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Toronto, Ontario, Canada, M5T 2S8

Canada, Quebec

[Not yet recruiting]
Montreal, Quebec, Canada, H1T 2M4

[Not yet recruiting]
Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Not yet recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

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References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	◉	◉	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: December 4, 2007 (v4)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2007

Overall Status: Recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	December 4, 2007
Last Update Posted:	December 6, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap-Eye

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.

6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron

Telephone: 866-549-8439

Email: VIEW1study@rtp.ppdi.com

Study Officials: Avner Ingerman, MD

Study Director

Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Not yet recruiting]

Birmingham, Alabama, United States, 35205

[Not yet recruiting]

Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]

Phoenix, Arizona, United States, 85014

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Beverly Hills, California, United States, 90211

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Fullerton, California, United States, 92835

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Los Angeles, California, United States, 90033

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Los Angeles, California, United States, 90048

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Hagerstown, Maryland, United States, 21740

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Towson, Maryland, United States, 21204

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Southfield, Michigan, United States, 48034

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Kansas City, Missouri, United States, 64111

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St. Louis, Missouri, United States, 63104

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Lynbrook, New York, United States, 11563

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United States, Oklahoma

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Oklahoma City, Oklahoma, United States, 73104

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Tulsa, Oklahoma, United States, 74104

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Ashland, Oregon, United States, 97520

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Portland, Oregon, United States, 97210

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Salem, Oregon, United States, 97302

United States, Pennsylvania

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Campbell, Pennsylvania, United States, 95008

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East Stroudsburg, Pennsylvania, United States, 18301

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Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

[Not yet recruiting]
Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

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Vancouver, British Columbia, Canada, V5Z 3N9

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Victoria, British Columbia, Canada, V8X 5G6

Canada, Nova Scotia

[Not yet recruiting]
Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Not yet recruiting]
London, Ontario, Canada, N6A 4G5

[Not yet recruiting]

Mississauga, Ontario, Canada, L4W 1W9

[Not yet recruiting]
Toronto, Ontario, Canada, M5C 2T2

[Recruiting]
Toronto, Ontario, Canada, M5T 2S8

Canada, Quebec

[Not yet recruiting]
Montreal, Quebec, Canada, H1T 2M4

[Not yet recruiting]
Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Not yet recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	◉	◉	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: November 14, 2007 (v3)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: August 2007

Overall Status: Recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	November 14, 2007
Last Update Posted:	November 16, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap-Eye

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.

6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron

Telephone: 866-549-8439

Email: VIEW1study@ppdi.com

Study Officials: Avner Ingerman, MD

Study Director

Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Not yet recruiting]

Birmingham, Alabama, United States, 35205

[Not yet recruiting]

Birmingham, Alabama, United States, 35223

United States, Arizona

[Recruiting]

Phoenix, Arizona, United States, 85014

[Recruiting]

Phoenix, Arizona, United States, 85020

[Recruiting]

Tucson, Arizona, United States, 85704

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Tucson, Arizona, United States, 85710

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Tucson, Arizona, United States, 85711

United States, California

[Recruiting]

Beverly Hills, California, United States, 90211

[Not yet recruiting]

Fullerton, California, United States, 92835

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Glendale, California, United States, 91203

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Irvine, California, United States, 92697

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La Jolla, California, United States, 92037

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Loma Linda, California, United States, 92354

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Los Angeles, California, United States, 90033

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Los Angeles, California, United States, 90048

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Menlo Park, California, United States, 94025

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Mountain View, California, United States, 94040

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Oakland, California, United States, 94609

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Palm Springs, California, United States, 92262

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San Diego, California, United States, 92120

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San Marino, California, United States, 91108

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Santa Ana, California, United States, 92705

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Ventura, California, United States, 93003

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Westlake Village, California, United States, 91361

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New London, Connecticut, United States, 06320

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Altamonte Springs, Florida, United States, 32701

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Boynton Beach, Florida, United States, 33426

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Paducah, Kentucky, United States, 42001

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New Orleans, Louisiana, United States, 70115

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Canada, Ontario

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Canada, Quebec

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Canada, Saskatchewan

[Not yet recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

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ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	◉	◉	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: August 17, 2007 (v2)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: August 2007

Overall Status: Recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	August 17, 2007
Last Update Posted:	August 21, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap-Eye

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.

6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Central Contact: Regeneron
Email: vegf.trap@regeneron.com

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

[Not yet recruiting]
Birmingham, Alabama, United States, 35205

[Not yet recruiting]
Birmingham, Alabama, United States, 35223

United States, Arizona

[Not yet recruiting]
Phoenix, Arizona, United States, 85014

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Phoenix, Arizona, United States, 85020

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Tucson, Arizona, United States, 85704

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United States, California

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Beverly Hills, California, United States, 90211

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Fullerton, California, United States, 92835

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Glendale, California, United States, 91203

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Irvine, California, United States, 92697

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La Jolla, California, United States, 92037

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Loma Linda, California, United States, 92354

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Los Angeles, California, United States, 90033

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Los Angeles, California, United States, 90048

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Menlo Park, California, United States, 94025

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Mountain View, California, United States, 94040

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Oakland, California, United States, 94609

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Palm Springs, California, United States, 92262

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Pasadena, California, United States, 91105

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Poway, California, United States, 92064

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Sacramento, California, United States, 95819

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San Diego, California, United States, 92120

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San Francisco, California, United States, 94107

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San Marino, California, United States, 91108

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Santa Ana, California, United States, 92705

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Ventura, California, United States, 93003

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Westlake Village, California, United States, 91361

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Yorba Linda, California, United States, 92887

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Denver, Colorado, United States, 80205

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Hamden, Connecticut, United States, 06518

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New Haven, Connecticut, United States, 06520

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New London, Connecticut, United States, 06320

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Canada, Alberta

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Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

[Not yet recruiting]
Vancouver, British Columbia, Canada, V5Z 3N9

[Not yet recruiting]
Victoria, British Columbia, Canada, V8X 5G6

Canada, Nova Scotia

[Not yet recruiting]
Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

[Not yet recruiting]
London, Ontario, Canada, N6A 4G5

[Not yet recruiting]
Mississauga, Ontario, Canada, L4W 1W9

[Not yet recruiting]
Toronto, Ontario, Canada, M5C 2T2

[Not yet recruiting]
Toronto, Ontario, Canada, M5T 2S8

Canada, Quebec

[Not yet recruiting]
Montreal, Quebec, Canada, H1T 2M4

[Not yet recruiting]
Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

[Not yet recruiting]
Regina, Saskatchewan, Canada, S4T 1A5

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations
3	○	○	November 14, 2007	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: July 31, 2007 (v1)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects With Wet AMD (VIEW 1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: July 2007

Overall Status: Not yet recruiting

Study Start: August 2007

Primary Completion:

Study Completion:

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that Met QC Criteria:	July 31, 2007
Last Update Posted:	August 1, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.
Detailed Description:	

Conditions

Conditions:	Neovascular Age-Related Macular Degeneration
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap-Eye

Outcome Measures

Primary Outcome Measures:

1. Primary measure will be visual acuity changes compared to baseline

Secondary Outcome Measures:

2. Secondary measures will be angiographic and anatomical changes compared to baseline.

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Key Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.

6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents.
4. Total lesion size > 12 disc areas (30.5 mm2, including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV, including pathologic myopia (spherical equivalent of -8 diopters or more negative, or axial length of 25 mm or more), ocular histoplasmosis syndrome, angioid streaks, choroidal rupture, or multifocal choroiditis in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Avner Ingerman, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

Tucson, Arizona, United States, 85711

United States, California

Beverly Hills, California, United States, 90211

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

San Marino, California, United States, 91108

Santa Ana, California, United States, 92705

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06520

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Delray Beach, Florida, United States, 33484

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33334

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32216

Jacksonville, Florida, United States, 32224

Margate, Florida, United States, 33063

Miami, Florida, United States, 33125

Miami, Florida, United States, 33136

Mount Dora, Florida, United States, 32757

Ocala, Florida, United States, 34472

Orlando, Florida, United States, 32806

Orlando, Florida, United States, 38203

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States, 34239

Stuart, Florida, United States, 34994

Sunrise, Florida, United States, 33351

Tampa, Florida, United States, 33607

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

Marietta, Georgia, United States, 30060

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Chicago, Illinois, United States, 60611

Chicago, Illinois, United States, 60637

Oak Brook, Illinois, United States, 60523

Springfield, Illinois, United States, 62701

Wheaton, Illinois, United States, 60187

United States, Indiana

Ft. Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

United States, Iowa

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Kentucky

Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

Metairie, Louisiana, United States, 70002

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Peabody, Massachusetts, United States, 01960

United States, Michigan

Ann Arbor, Michigan, United States, 48105

Battle Creek, Michigan, United States, 49015

East Lansing, Michigan, United States, 48823

Grand Blanc, Michigan, United States, 48439

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63104

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68124

Omaha, Nebraska, United States, 68131

United States, Nevada

Las Vegas, Nevada, United States, 89144

United States, New Hampshire

Lebanon, New Hampshire, United States, 03756

United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

Newark, New Jersey, United States, 07103

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Bronxville, New York, United States, 10708

Bronx, New York, United States, 10467

Brooklyn, New York, United States, 11223

Great Neck, New York, United States, 11021

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Rochester, New York, United States, 14618

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

United States, North Carolina

Asheville, North Carolina, United States, 28803

Charlotte, North Carolina, United States, 28210

Hendersonville, North Carolina, United States, 28791

Raleigh, North Carolina, United States, 27607

Raleigh, North Carolina, United States, 27612

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

United States, North Dakota

Fargo, North Dakota, United States, 58103

United States, Ohio

Canton, Ohio, United States, 44718

Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Cleveland, Ohio, United States, 44122

Cleveland, Ohio, United States, 44195

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43606

Toledo, Ohio, United States, 43608

Toledo, Ohio, United States, 43615

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

Tulsa, Oklahoma, United States, 74104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Camp Hill, Pennsylvania, United States, 17011

Campbell, Pennsylvania, United States, 95008

East Stroudsburg, Pennsylvania, United States, 18301

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

Pittsburgh, Pennsylvania, United States, 15219

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Columbia, South Carolina, United States, 29204

Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

Rock Hill, South Carolina, United States, 29732

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78133

San Antonio, Texas, United States, 78240

United States, Utah

Ogden, Utah, United States, 84403

Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Seattle, Washington, United States, 98195

Silverdale, Washington, United States, 98383

Spokane, Washington, United States, 99203

United States, Wisconsin

Madison, Wisconsin, United States, 53715

Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8X 5G6

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M5C 2T2

Toronto, Ontario, Canada, M5T 2S8

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	◉	◉	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: December 20, 2012 (v18)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2012

Overall Status: Completed

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Actual]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	April 13, 2012
Results First Posted:	April 16, 2012 [Estimate]
Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	December 20, 2012
Last Update Posted:	December 28, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase 3, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: ranibizumab 0.5mg Q4	Biological: ranibizumab Participants received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • Lucentis

Arms	Assigned Interventions
Experimental: aflibercept injection 2.0mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 0.5mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 0.5mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 2.0mg Q8	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. Early Treatment Diabetic Retinopathy Study (ETDRS) Best Corrected Visual Acuity (BCVA) of: letter score of 73 to 25 (20/40 to 20/320) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.

5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

United States, Iowa

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Kentucky

Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

United States, Michigan

Ann Arbor, Michigan, United States, 48105

Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

Las Vegas, Nevada, United States, 89144

United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

Syracuse, New York, United States, 13224

United States, North Carolina

Asheville, North Carolina, United States, 28803

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43608

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsberg, Pennsylvania, United States, 15231

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Charleston, South Carolina, United States, 29414

Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

Corpus Cristi, Texas, United States, 78413

Dallas, Texas, United States, 75390

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Fairfax, Virginia, United States, 22031

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Silverdale, Washington, United States, 98383

United States, Wisconsin

Madison, Wisconsin, United States, 53715

Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Ottawa, Ontario, Canada, K1H8L6

Toronto, Ontario, Canada, M4N3M5

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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Study Results

Participant Flow

Recruitment Details	The study was conducted at 164 sites in the United States and Canada. Recruitment period: 02 Aug 2007 to 15 Sep 2009.

Pre-assignment Details	2063 patients were screened, 1217 randomized, and 1215 included in the Safety Analysis Set (SAF). The Full Analysis Set (FAS) included 1210 patients with at least 1 post-baseline assessment. The Per Protocol Set (PPS) included 1089 patients who received ≥ 9 doses of study drug and attended ≥ 9 scheduled visits during the first year.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and received sham injections at interim monthly visits.

Overall Study

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
Started	306	304	304	303
Patients Received Treatment (SAF)	304	304	304	303
Full Analysis Set (FAS) Population	304	304	301	301
Per Protocol Set (PPS) Population	269	285	270	265
Completed	284	293	277	276
Not Completed	22	11	27	27
Adverse Event	4	3	5	4
Death	3	1	2	7
Lack of Efficacy	0	0	2	2
Lost to Follow-up	1	2	4	4
OTHER	1	0	4	1
Protocol Violation	3	0	3	1
Withdrawal by Subject	10	5	7	8

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

Baseline Measures

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants		304	304	304	303	1215
Age Continuous [1] Mean (Standard Deviation) Unit of measure: years	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
		78.2 (0 to 0)	77.7 (0 to 0)	78.3 (0 to 0)	77.9 (0 to 0)	78.0 (8.00)
		[1] Measure Description: SAF population used for analysis.				
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	Female	172 56.58%	194 63.82%	169 55.59%	179 59.08%	714 58.77%
	Male	132 43.42%	110 36.18%	135 44.41%	124 40.92%	501 41.23%
Ethnicity (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	Hispanic or Latino	7 2.3% (0 to 0)	11 3.62% (0 to 0)	11 3.62% (0 to 0)	12 3.96% (0 to 0)	41 3.37%
	Not Hispanic or Latino	297 97.7%	293 96.38%	293 96.38%	291 96.04%	1174 96.63%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%	0 0%
		[1] Measure Description: SAF population used for analysis.				

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Race (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	American Indian or Alaska Native	2 0.66% (0 to 0)	0 0% (0 to 0)	2 0.66% (0 to 0)	1 0.33% (0 to 0)	5 0.41%
	Asian	0 0% (0 to 0)	3 0.99% (0 to 0)	5 1.64% (0 to 0)	4 1.32% (0 to 0)	12 0.99%
	Native Hawaiian or Other Pacific Islander	1 0.33% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	2 0.16%
	Black or African American	1 0.33% (0 to 0)	1 0.33% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	3 0.25%
	White	296 97.37% (0 to 0)	295 97.04% (0 to 0)	294 96.71% (0 to 0)	289 95.38% (0 to 0)	1174 96.63%
	More than one race	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	1 0.08%
	Unknown or Not Reported	4 1.32% (0 to 0)	5 1.64% (0 to 0)	3 0.99% (0 to 0)	6 1.98% (0 to 0)	18 1.48%
		[1] Measure Description: SAF population used for analysis.				
Baseline National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1] Mean (Standard Deviation)	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Unit of measure: scores on a scale		71.7 (0 to 0)	70.4 (0 to 0)	71.1 (0 to 0)	69.5 (0 to 0)	70.7 (17.11)
		[1] Measure Description: SAF population used for analysis. The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.				
Baseline Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.52 (0 to 0)	6.59 (0 to 0)	6.49 (0 to 0)	6.56 (0 to 0)	6.54 (4.968)
		[1] Measure Description: SAF population used for analysis.				
Baseline Lesion Type [1] Measure type: Number Unit of measure: patients	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Occult		115 (0 to 0)	110 (0 to 0)	123 (0 to 0)	118 (0 to 0)	466 38.35%
Minimally Classic		101 (0 to 0)	105 (0 to 0)	97 (0 to 0)	112 (0 to 0)	415 34.16%
Predominantly Classic		82 (0 to 0)	87 (0 to 0)	82 (0 to 0)	71 (0 to 0)	322 26.5%
Missing		6 (0 to 0)	2 (0 to 0)	2 (0 to 0)	2 (0 to 0)	12 0.99%
		[1] Measure Description: SAF population used for analysis.				
Baseline Total Lesion Size [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.99 (0 to 0)	6.98 (0 to 0)	6.96 (0 to 0)	6.88 (0 to 0)	6.95 (5.202)

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
		[1] Measure Description: SAF population used for analysis.				
Baseline Best Corrected Visual Acuity (BCVA) [1] Mean (Standard Deviation) Unit of measure: letters read	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
		54.0 (0 to 0)	55.2 (0 to 0)	55.5 (0 to 0)	55.7 (0 to 0)	55.1 (13.14)
		[1] Measure Description: SAF population used for analysis. BCVA assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) chart. For BCVA tested via the 4 meter ETDRS protocol, 83 letters or more would represent 20/20 vision or better which would be considered an excellent outcome. Although, the ETDRS charts include 100 letters as the maximum possible score. The worst outcome is 0 letters read.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Defined "maintenance of vision" as patients who lost fewer than 15 letters in Early Treatment Diabetic Retinopathy Study (ETDRS) letter score compared to baseline.
Time Frame	Baseline and at week 52

Analysis Population Description

PPS population used for analysis.

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	269	285	270	265	1089
Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: percentage of patients	94.4 (0)	95.1 (0)	95.9 (0)	95.1 (0)	95.1 (0)

Statistical Analysis 1 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.4 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A positive value favors IAI 2.0Q4. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 2 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI (EYLEA, VEGF Trap-Eye).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.5
	Confidence Interval	(2-sided) 95.1% -5.1 to 2.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A negative value favors the IAI 0.5Q4 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 3 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI (EYLEA, VEGF Trap-Eye).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.5 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A negative value favors the IAI 2.0Q8 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	8.1 (15.25)	10.9 (13.77)	6.9 (13.41)	7.9 (15.00)	8.5 (14.44)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0054
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	3.15
	Confidence Interval	(2-sided) 95.1% 0.92 to 5.37
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4793
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.80
	Confidence Interval	(2-sided) 95.1% -3.03 to 1.43
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8179
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares Means
	Estimated Value	0.26
	Confidence Interval	(2-sided) 95.1% -1.97 to 2.49
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q8.

3. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF. Measure Type: Number Unit of Measure: percentage of patients	30.9 (0)	37.5 (0)	24.9 (0)	30.6 (0)	31.1 (0)

Statistical Analysis 1 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1042
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	6.6
	Confidence Interval	(2-sided) 95.1% -1.0 to 14.1
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1037
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-6.0
	Confidence Interval	(2-sided) 95.1% -13.2 to 1.2
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.93
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.4
	Confidence Interval	(2-sided) 95.1% -7.7 to 7.0
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q8.

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.
Time Frame	Baseline and at Week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: scores on a scale	4.9 (14.01)	6.7 (13.50)	4.5 (11.87)	5.1 (14.74)	5.3 (13.59)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2090
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences Least Squares means
	Estimated Value	1.28
	Confidence Interval	(2-sided) 95.1% -0.73 to 3.28
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5128
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.67
	Confidence Interval	(2-sided) 95.1% -2.69 to 1.35
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5579
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.60
	Confidence Interval	(2-sided) 95.1% -2.61 to 1.42
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)
Measure Description	CNV area values measured in square millimeters (mm^2); lower values represent better outcomes.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.2 (5.59)	-4.6 (5.47)	-3.5 (5.27)	-3.4 (6.02)	-3.9 (5.61)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3575
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.33
	Confidence Interval	(2-sided) 95.1% -1.04 to 0.38
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 2.0Q4

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0507
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.71
	Confidence Interval	(2-sided) 95.1% -0.01 to 1.42
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 0.5Q4

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0173
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.86
	Confidence Interval	(2-sided) 95.1% 0.15 to 1.58
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 2.0Q8

Reported Adverse Events

Time Frame	AEs reported from Day 1 to Wk 96. Yr 1 of tx (Day 1 to Wk 52): 21-day screening period followed by administration of study drug every 4 or 8 wks including sham injections at interim study visits (when study drug was not administered) for 48 wks.
Adverse Event Reporting Description	Yr 2 of tx (Wk 52 to Wk 96): Pts evaluated every 4 wks and received IVT injections of study drug (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 wks.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of ranibizumab (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.

IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	94/304 (30.92%)	70/304 (23.03%)	88/304 (28.95%)	90/303 (29.7%)
Blood and lymphatic system disorders				
ANAEMIA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
COAGULOPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Congenital, familial and genetic disorders				

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ARTERIOVENOUS MALFORMATION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Ear and labyrinth disorders				
ACUTE CORONARY SYNDROME [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
ACUTE MYOCARDIAL INFARCTION [A*]	1/304 (0.33%)	2/304 (0.66%)	2/304 (0.66%)	1/303 (0.33%)
ANGINA UNSTABLE [A*]	3/304 (0.99%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
AORTIC VALVE STENOSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ARRHYTHMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ARTERIOSCLEROSIS CORONARY ARTERY [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ATRIAL FIBRILLATION [A*]	3/304 (0.99%)	2/304 (0.66%)	7/304 (2.3%)	7/303 (2.31%)
ATRIOVENTRICULAR BLOCK FIRST DEGREE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BRADYCARDIA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CARDIAC ARREST [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
CARDIAC FAILURE ACUTE [A*]	1/304 (0.33%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
CARDIAC FAILURE CHRONIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CARDIAC FAILURE CONGESTIVE [A*]	4/304 (1.32%)	2/304 (0.66%)	4/304 (1.32%)	8/303 (2.64%)
CARDIO-RESPIRATORY ARREST [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CARDIOMYOPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CORONARY ARTERY DISEASE [A*]	5/304 (1.64%)	0/304 (0%)	6/304 (1.97%)	1/303 (0.33%)
CORONARY ARTERY OCCLUSION [A*]	1/304 (0.33%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
CORONARY ARTERY STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
INTRACARDIAC THROMBUS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MENIERE'S DISEASE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MITRAL VALVE INCOMPETENCE [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
MYOCARDIAL INFARCTION [A*]	6/304 (1.97%)	1/304 (0.33%)	5/304 (1.64%)	2/303 (0.66%)
MYOCARDIAL ISCHAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PERICARDIAL EFFUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SICK SINUS SYNDROME [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUPRAVENTRICULAR TACHYCARDIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TACHYARRHYTHMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
TACHYCARDIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
VENTRICULAR FIBRILLATION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VENTRICULAR TACHYCARDIA [A*]	0/304 (0%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
VERTIGO [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
Eye disorders				
AGE-RELATED MACULAR DEGENERATION [A [1]*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ANGLE CLOSURE GLAUCOMA A [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BLEPHARITIS A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BLINDNESS TRANSIENT A [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CATARACT A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOROIDAL HAEMORRHAGE A [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOROIDAL NEOVASCULARISATION A [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONJUNCTIVAL HAEMORRHAGE A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONJUNCTIVITIS A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DRY Eye disorders A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders IRRITATION A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders PAIN A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders PRURITUS A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOREIGN BODY SENSATION IN Eye disordersS A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
KERATITIS A [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LACRIMATION INCREASED A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MACULAR DEGENERATION A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MACULAR HOLE A [2]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MACULOPATHY A [1]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
POSTERIOR CAPSULE OPACIFICATION [A] [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PSEUDOENDOPHTHALMITIS [A] [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL DEGENERATION [A] [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RETINAL DETACHMENT [A] [1]*	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
RETINAL HAEMORRHAGE [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL OEDEMA [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL PIGMENT EPITHELIAL TEar and labyrinth disorders [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL PIGMENT EPITHELIOPATHY [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL TEar and labyrinth disorders [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
UVEITIS [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
VISION BLURRED [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VISUAL ACUITY REDUCED [A] [1]*	1/304 (0.33%)	1/304 (0.33%)	3/304 (0.99%)	0/303 (0%)
VITREOUS DETACHMENT [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VITREOUS FLOATERS [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VITREOUS HAEMORRHAGE [A] [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Gastrointestinal disorders				
ABDOMINAL HERNIA [A]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ABDOMINAL HERNIA OBSTRUCTIVE [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ASTHENIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CATHETER SITE HAEMATOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CHEST PAIN [A*]	2/304 (0.66%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
COLITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
COLITIS ISCHAEMIC [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
COLONIC POLYP [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONSTIPATION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DEATH [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
DEVICE DISLOCATION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
DIARRHOEA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DRUG WITHDRAWAL SYNDROME [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DUODENAL ULCER HAEMORRHAGE [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DYSPHAGIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOOD POISONING [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
GASTRIC HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTRIC ULCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS EROSIVE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
GASTROINTESTINAL DISORDER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
GASTROINTESTINAL MOTILITY DISORDER [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROINTESTINAL OBSTRUCTION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
GASTROOESOPHAGEAL REFLUX DISEASE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMATOCHEZIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMORRHOIDS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HIATUS HERNIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ILEUS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
INGUINAL HERNIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INTESTINAL OBSTRUCTION [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
LOWER GASTROINTESTINAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
NAUSEA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
NON-CARDIAC CHEST PAIN [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
OESOPHAGEAL ULCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PANCREATITIS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
PYREXIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SMALL INTESTINAL OBSTRUCTION [A*]	2/304 (0.66%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
Hepatobiliary disorders				
BILE DUCT STONE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CHOLANGITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHOLECYSTITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
CHOLECYSTITIS ACUTE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOLECYSTITIS CHRONIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHOLELITHIASIS [A*]	1/304 (0.33%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
PORTAL HYPERTENSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PORTAL VEIN THROMBOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Immune system disorders				
DRUG HYPERSENSITIVITY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Infections and infestations				
ANAL ABSCESS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ANORECTAL CELLULITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ARTHRITIS BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
BACTERIAL DISEASE CARRIER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BRONCHITIS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	3/303 (0.99%)
CELLULITIS [A*]	3/304 (0.99%)	3/304 (0.99%)	2/304 (0.66%)	0/303 (0%)
CLOSTRIDIAL Infections and infestationsION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
CLOSTRIDIUM DIFFICILE COLITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DEVICE RELATED Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
DIVERTICULITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
ENCEPHALITIS VIRAL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOCARDITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOPHTHALMITIS [A [1]*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ESCHERICHIA URINARY TRACT Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROENTERITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
GASTROENTERITIS VIRAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
INFLUENZA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
KLEBSIELLA BACTERAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LABYRINTHITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LOBAR PNEUMONIA [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
LUNG Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
NASOPHARYNGITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PHARYNGITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PNEUMONIA [A*]	14/304 (4.61%)	6/304 (1.97%)	5/304 (1.64%)	8/303 (2.64%)
PYELONEPHRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SCROTAL ABSCESS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SEPSIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SEPTIC SHOCK [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SINUSITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SINUSITIS FUNGAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
STAPHYLOCOCCAL BACTERAEMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
UPPER RESPIRATORY TRACT Infections and infestationsION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
URINARY TRACT Infections and infestationsION [A*]	1/304 (0.33%)	3/304 (0.99%)	0/304 (0%)	0/303 (0%)
URINARY TRACT Infections and infestationsION BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
URINARY TRACT Infections and infestationsION STAPHYLOCOCCAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
UROSEPSIS [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
VESTIBULAR NEURONITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL Infections and infestationsION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL PERICARDITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
WOUND Infections and infestationsION BACTERIAL [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Injury, poisoning and procedural complications				
ACCIDENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CERVICAL VERTEBRAL FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONCUSSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
FALL [A*]	8/304 (2.63%)	13/304 (4.28%)	7/304 (2.3%)	16/303 (5.28%)
FEMORAL NECK FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
FEMUR FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
FIBULA FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOOT FRACTURE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
HEAD Injury, poisoning and procedural complications [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HIP FRACTURE [A*]	1/304 (0.33%)	4/304 (1.32%)	2/304 (0.66%)	1/303 (0.33%)
HUMERUS FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	3/304 (0.99%)	0/303 (0%)
INCISIONAL HERNIA, OBSTRUCTIVE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INCORRECT DOSE ADMINISTERED [A [2]*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
JOINT DISLOCATION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
JOINT Injury, poisoning and procedural complications [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LUMBAR VERTEBRAL FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MENISCUS LESION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
POST LAMINECTOMY SYNDROME [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PROCEDURAL PAIN [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PUBIS FRACTURE [A*]	1/304 (0.33%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
RIB FRACTURE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
ROAD TRAFFIC ACCIDENT [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SNAKE BITE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SPINAL COMPRESSION FRACTURE [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
SPINAL FRACTURE [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
STERNAL FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SUBCUTANEOUS HAEMATOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUBDURAL HAEMATOMA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
TIBIA FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
TRAUMATIC BRAIN Injury, poisoning and procedural complications [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
UPPER LIMB FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
VASCULAR PSEUDOANEURYSM [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Investigations				
Blood and lymphatic system disorders GLUCOSE INCREASED [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Blood and lymphatic system disorders PRESSURE INCREASED [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
Blood and lymphatic system disorders PRESSURE ORTHOSTATIC ABNORMAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
INTRAOCULAR PRESSURE INCREASED [A [1]*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Metabolism and nutrition disorders				
DEHYDRATION [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
DIABETES MELLITUS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
DIABETES MELLITUS INADEQUATE CONTROL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ELECTROLYTE IMBALANCE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPERKALAEMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HYPOGLYCAEMIA [A*]	0/304 (0%)	2/304 (0.66%)	1/304 (0.33%)	0/303 (0%)
HYPOKALAEMIA [A*]	2/304 (0.66%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPONATRAEMIA [A*]	2/304 (0.66%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
MALNUTRITION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HYPOGLYCAEMIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ARTHRITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
ARTHROPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BACK PAIN [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CERVICAL SPINAL STENOSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
INTERVERTEBRAL DISC DEGENERATION [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
INTERVERTEBRAL DISC PROTRUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUMBAR SPINAL STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
OSTEOARTHRITIS [A*]	4/304 (1.32%)	1/304 (0.33%)	3/304 (0.99%)	1/303 (0.33%)
OSTEONECROSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PAIN IN EXTREMITY [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RHABDOMYOLYSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SPINAL COLUMN STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPINAL OSTEOARTHRITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPONDYLOLISTHESIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
ATYPICAL FIBROXANTHOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
B-CELL LYMPHOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BASAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BLADDER TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	2/304 (0.66%)	1/303 (0.33%)
BLADDER TRANSITIONAL CELL CARCINOMA RECURRENT [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BRAIN NEOPLASM [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
BREAST Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	2/303 (0.66%)
BREAST Neoplasms benign, malignant and unspecified (incl cysts and polyps) IN SITU [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
BRONCHIOLOALVEOLAR CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CARDIAC MYXOMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CHRONIC LYMPHOCYTIC LEUKAEMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
COLON Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
COLON Neoplasms benign, malignant and unspecified (incl cysts and polyps) RECURRENT [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOMETRIAL Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
HEPATIC NEOPLASM MALIGNANT [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HEPATIC Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LEUKAEMIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
LUNG NEOPLASM [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUNG NEOPLASM MALIGNANT [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
LUNG SQUAMOUS CELL CARCINOMA STAGE II [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MALIGNANT MELANOMA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTASES TO CENTRAL NERVOUS SYSTEM [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
METASTASES TO Hepatobiliary disorders [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTASES TO LUNG [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
METASTASES TO LYMPH NODES [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTATIC NEOPLASM [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
NEOPLASM MALIGNANT [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
NON-SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
NON-SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) STAGE IV [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
OESOPHAGEAL ADENOCARCINOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
PROSTATE Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	1/304 (0.33%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
PROSTATE Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
RECTAL Neoplasms benign, malignant and unspecified (incl cysts and polyps) STAGE III [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
RECTOSIGMOID Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RENAL CELL CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SALIVARY GLAND Neoplasms benign, malignant and unspecified (incl cysts and polyps) RECURRENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SMALL CELL LUNG Neoplasms benign,malignant & unspecified(incl cysts and polyps)STAGE UNSPECIFIED [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SQUAMOUS CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SQUAMOUS CELL CARCINOMA OF Skin and subcutaneous tissue disorders [A*]	5/304 (1.64%)	3/304 (0.99%)	2/304 (0.66%)	4/303 (1.32%)
THYROID Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TONSIL Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TUMOUR HAEMORRHAGE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
WALDENSTROM'S MACROGLOBULINAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Nervous system disorders				
APHASIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BALANCE DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CAROTID ARTERY DISEASE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CAROTID ARTERY STENOSIS [A*]	0/304 (0%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
CEREBELLAR INFARCTION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CEREBRAL ARTERY THROMBOSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CEREBRAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBRAL INFARCTION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBROVASCULAR ACCIDENT [A*]	2/304 (0.66%)	3/304 (0.99%)	1/304 (0.33%)	5/303 (1.65%)
COMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONVULSION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DEMENTIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DIZZINESS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
EMBOLIC STROKE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HEADACHE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ISCHAEMIC CEREBRAL INFARCTION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LACUNAR INFARCTION [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LOSS OF CONSCIOUSNESS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
METABOLIC ENCEPHALOPATHY [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PRESYNCOPE [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
SPINAL CORD COMPRESSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SUBARACHNOID HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
SYNCOPE [A*]	3/304 (0.99%)	1/304 (0.33%)	3/304 (0.99%)	1/303 (0.33%)
TRANSIENT GLOBAL AMNESIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
TRANSIENT ISCHAEMIC ATTACK [A*]	0/304 (0%)	3/304 (0.99%)	7/304 (2.3%)	5/303 (1.65%)
Psychiatric disorders				
CONFUSIONAL STATE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MENTAL STATUS CHANGES [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Psychiatric disordersOTIC DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Renal and urinary disorders				
CALCULUS BLADDER [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CALCULUS URETERIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HAEMATURIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HYDRONEPHROSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RENAL FAILURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RENAL FAILURE ACUTE [A*]	0/304 (0%)	3/304 (0.99%)	2/304 (0.66%)	2/303 (0.66%)
RENAL FAILURE CHRONIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Reproductive system and breast disorders				
CYSTOCELE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RECTOCELE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Respiratory, thoracic and mediastinal disorders				
ACUTE RESPIRATORY FAILURE [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
APNOEIC ATTACK [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ASTHMA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A*]	3/304 (0.99%)	3/304 (0.99%)	6/304 (1.97%)	6/303 (1.98%)
COUGH [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
DYSPNOEA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
EMPHYSEMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PLEURAL EFFUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PNEUMONIA ASPIRATION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
PNEUMONITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
PULMONARY EMBOLISM [A*]	0/304 (0%)	2/304 (0.66%)	1/304 (0.33%)	2/303 (0.66%)
PULMONARY FIBROSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PULMONARY MASS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PULMONARY OEDEMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RESPIRATORY DISTRESS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RESPIRATORY FAILURE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RESTRICTIVE PULMONARY DISEASE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TRACHEAL MASS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Skin and subcutaneous tissue disorders				
ANGIOEDEMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
Surgical and medical procedures				
CHOLECYSTECTOMY [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
MICROGRAPHIC Skin and subcutaneous tissue disorders SURGERY [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
Vascular disorders				
AORTIC ANEURYSM [A*]	1/304 (0.33%)	2/304 (0.66%)	1/304 (0.33%)	0/303 (0%)
AORTIC ANEURYSM RUPTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
AORTIC STENOSIS [A*]	1/304 (0.33%)	1/304 (0.33%)	2/304 (0.66%)	1/303 (0.33%)
ARTERIOSCLEROSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DEEP VEIN THROMBOSIS [A*]	1/304 (0.33%)	1/304 (0.33%)	1/304 (0.33%)	2/303 (0.66%)
FEMORAL ARTERY ANEURYSM [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HAEMATOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPERTENSION [A*]	2/304 (0.66%)	0/304 (0%)	3/304 (0.99%)	0/303 (0%)
HYPOTENSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ILIAC ARTERY OCCLUSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
LYMPHATIC FISTULA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LYMPHOCELE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ORTHOSTATIC HYPOTENSION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PERIPHERAL ARTERY ANEURYSM [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PERIPHERAL VASCULAR DISORDER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PHLEBITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
PHLEBITIS DEEP A*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HAEMORRHAGIC A*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, Medra Version 14.0

[1] Ocular Fellow Eye disorders

[2] Ocular Study Eye disorders

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	261/304 (85.86%)	254/304 (83.55%)	262/304 (86.18%)	258/303 (85.15%)
Ear and labyrinth disorders				
ATRIOVENTRICULAR BLOCK FIRST DEGREE A*	16/304 (5.26%)	18/304 (5.92%)	8/304 (2.63%)	9/303 (2.97%)
Eye disorders				
AGE-RELATED MACULAR DEGENERATION A [1]*	21/304 (6.91%)	16/304 (5.26%)	12/304 (3.95%)	15/303 (4.95%)
BLEPHARITIS A [1]*	16/304 (5.26%)	18/304 (5.92%)	14/304 (4.61%)	14/303 (4.62%)
CATARACT A [1]*	10/304 (3.29%)	17/304 (5.59%)	10/304 (3.29%)	10/303 (3.3%)
CHOROIDAL NEOVASCULARISATION A [1]*	17/304 (5.59%)	10/304 (3.29%)	13/304 (4.28%)	9/303 (2.97%)
CONJUNCTIVAL HAEMORRHAGE A [1]*	16/304 (5.26%)	17/304 (5.59%)	16/304 (5.26%)	19/303 (6.27%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
DRY Eye disorders [A] [2]*	12/304 (3.95%)	16/304 (5.26%)	10/304 (3.29%)	14/303 (4.62%)
Eye disorders IRRITATION [A] [2]*	19/304 (6.25%)	13/304 (4.28%)	15/304 (4.93%)	16/303 (5.28%)
Eye disorders PAIN [A] [2]*	34/304 (11.18%)	39/304 (12.83%)	35/304 (11.51%)	31/303 (10.23%)
Eye disorders PRURITUS [A] [2]*	11/304 (3.62%)	16/304 (5.26%)	10/304 (3.29%)	6/303 (1.98%)
FOREIGN BODY SENSATION IN Eye disordersS [A] [2]*	9/304 (2.96%)	10/304 (3.29%)	10/304 (3.29%)	19/303 (6.27%)
LACRIMATION INCREASED [A] [2]*	11/304 (3.62%)	11/304 (3.62%)	15/304 (4.93%)	16/303 (5.28%)
MACULAR DEGENERATION [A] [1]*	22/304 (7.24%)	14/304 (4.61%)	21/304 (6.91%)	14/303 (4.62%)
RETINAL HAEMORRHAGE [A] [1]*	43/304 (14.14%)	36/304 (11.84%)	36/304 (11.84%)	22/303 (7.26%)
RETINAL OEDEMA [A] [1]*	18/304 (5.92%)	8/304 (2.63%)	12/304 (3.95%)	11/303 (3.63%)
RETINAL PIGMENT EPITHELIOPATHY [A] [2]*	14/304 (4.61%)	18/304 (5.92%)	17/304 (5.59%)	14/303 (4.62%)
VISION BLURRED [A] [2]*	12/304 (3.95%)	18/304 (5.92%)	17/304 (5.59%)	13/303 (4.29%)
VISUAL ACUITY REDUCED [A] [1]*	27/304 (8.88%)	10/304 (3.29%)	20/304 (6.58%)	19/303 (6.27%)
VITREOUS DETACHMENT [A] [1]*	16/304 (5.26%)	24/304 (7.89%)	25/304 (8.22%)	24/303 (7.92%)
VITREOUS FLOATERS [A] [2]*	47/304 (15.46%)	49/304 (16.12%)	30/304 (9.87%)	29/303 (9.57%)
Gastrointestinal disorders				
DIARRHOEA [A]*	18/304 (5.92%)	18/304 (5.92%)	8/304 (2.63%)	9/303 (2.97%)
NAUSEA [A]*	15/304 (4.93%)	16/304 (5.26%)	15/304 (4.93%)	15/303 (4.95%)
Infections and infestations				
BRONCHITIS [A]*	23/304 (7.57%)	19/304 (6.25%)	16/304 (5.26%)	24/303 (7.92%)
NASOPHARYNGITIS [A]*	36/304 (11.84%)	46/304 (15.13%)	41/304 (13.49%)	39/303 (12.87%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SINUSITIS [A*]	18/304 (5.92%)	13/304 (4.28%)	17/304 (5.59%)	14/303 (4.62%)
UPPER RESPIRATORY TRACT Infections and infestationsION [A*]	18/304 (5.92%)	18/304 (5.92%)	19/304 (6.25%)	26/303 (8.58%)
URINARY TRACT Infections and infestationsION [A*]	26/304 (8.55%)	22/304 (7.24%)	25/304 (8.22%)	23/303 (7.59%)
Injury, poisoning and procedural complications				
FALL [A*]	19/304 (6.25%)	13/304 (4.28%)	15/304 (4.93%)	21/303 (6.93%)
Investigations				
Blood and lymphatic system disorders GLUCOSE INCREASED [A*]	13/304 (4.28%)	12/304 (3.95%)	17/304 (5.59%)	16/303 (5.28%)
INTRAOCULAR PRESSURE INCREASED [A [1]*]	16/304 (5.26%)	8/304 (2.63%)	15/304 (4.93%)	15/303 (4.95%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA [A*]	17/304 (5.59%)	18/304 (5.92%)	17/304 (5.59%)	8/303 (2.64%)
BACK PAIN [A*]	11/304 (3.62%)	14/304 (4.61%)	13/304 (4.28%)	16/303 (5.28%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
BASAL CELL CARCINOMA [A*]	5/304 (1.64%)	11/304 (3.62%)	15/304 (4.93%)	17/303 (5.61%)
Nervous system disorders				
HEADACHE [A*]	21/304 (6.91%)	14/304 (4.61%)	16/304 (5.26%)	15/303 (4.95%)
Respiratory, thoracic and mediastinal disorders				
COUGH [A*]	16/304 (5.26%)	13/304 (4.28%)	10/304 (3.29%)	13/303 (4.29%)
Vascular disorders				

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
HYPERTENSION [A*]	35/304 (11.51%)	30/304 (9.87%)	32/304 (10.53%)	33/303 (10.89%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, Medra Version 14.0

[1] Ocular Fellow Eye disorders

[2] Ocular Study Eye disorders

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals
Phone:
Email: clinicaltrials@regeneron.com

Mylan Exhibit 1017
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History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	○	○	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	◉	◉	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: December 17, 2012 (v17)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2012

Overall Status: Completed

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Actual]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	April 13, 2012
Results First Posted:	April 16, 2012 [Estimate]
Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	December 17, 2012
Last Update Posted:	December 20, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase 3, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: ranibizumab 0.5mg Q4	Biological: ranibizumab Participants received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • Lucentis

Arms	Assigned Interventions
Experimental: aflibercept injection 2.0mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 0.5mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 0.5mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 2.0mg Q8	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. Early Treatment Diabetic Retinopathy Study (ETDRS) Best Corrected Visual Acuity (BCVA) of: letter score of 73 to 25 (20/40 to 20/320) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.

5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

United States, Iowa

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Kentucky

Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

United States, Michigan

Ann Arbor, Michigan, United States, 48105

Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

Las Vegas, Nevada, United States, 89144

United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

Syracuse, New York, United States, 13224

United States, North Carolina

Asheville, North Carolina, United States, 28803

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43608

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsberg, Pennsylvania, United States, 15231

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Charleston, South Carolina, United States, 29414

Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

Corpus Cristi, Texas, United States, 78413

Dallas, Texas, United States, 75390

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Fairfax, Virginia, United States, 22031

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Silverdale, Washington, United States, 98383

United States, Wisconsin

Madison, Wisconsin, United States, 53715

Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Ottawa, Ontario, Canada, K1H8L6

Toronto, Ontario, Canada, M4N3M5

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

IPDSharing

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References

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Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 164 sites in the United States and Canada. Recruitment period: 02 Aug 2007 to 15 Sep 2009.

Pre-assignment Details	2063 patients were screened, 1217 randomized, and 1215 included in the Safety Analysis Set (SAF). The Full Analysis Set (FAS) included 1210 patients with at least 1 post-baseline assessment. The Per Protocol Set (PPS) included 1089 patients who received ≥ 9 doses of study drug and attended ≥ 9 scheduled visits during the first year.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and received sham injections at interim monthly visits.

Overall Study

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
Started	306	304	304	303
Patients Received Treatment (SAF)	304	304	304	303
Full Analysis Set (FAS) Population	304	304	301	301
Per Protocol Set (PPS) Population	269	285	270	265
Completed	284	293	277	276
Not Completed	22	11	27	27
Adverse Event	4	3	5	4
Death	3	1	2	7
Lack of Efficacy	0	0	2	2
Lost to Follow-up	1	2	4	4
OTHER	1	0	4	1
Protocol Violation	3	0	3	1
Withdrawal by Subject	10	5	7	8

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

Baseline Measures

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants		304	304	304	303	1215
Age Continuous [1] Mean (Standard Deviation) Unit of measure: years	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
		78.2 (0 to 0)	77.7 (0 to 0)	78.3 (0 to 0)	77.9 (0 to 0)	78.0 (8.00)
		[1] Measure Description: SAF population used for analysis.				
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	Female	172 56.58%	194 63.82%	169 55.59%	179 59.08%	714 58.77%
	Male	132 43.42%	110 36.18%	135 44.41%	124 40.92%	501 41.23%
Ethnicity (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	Hispanic or Latino	7 2.3% (0 to 0)	11 3.62% (0 to 0)	11 3.62% (0 to 0)	12 3.96% (0 to 0)	41 3.37%
	Not Hispanic or Latino	297 97.7%	293 96.38%	293 96.38%	291 96.04%	1174 96.63%
	Unknown or Not Reported	0 0%	0 0%	0 0%	0 0%	0 0%
		[1] Measure Description: SAF population used for analysis.				

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Race (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	American Indian or Alaska Native	2 0.66% (0 to 0)	0 0% (0 to 0)	2 0.66% (0 to 0)	1 0.33% (0 to 0)	5 0.41%
	Asian	0 0% (0 to 0)	3 0.99% (0 to 0)	5 1.64% (0 to 0)	4 1.32% (0 to 0)	12 0.99%
	Native Hawaiian or Other Pacific Islander	1 0.33% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	2 0.16%
	Black or African American	1 0.33% (0 to 0)	1 0.33% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	3 0.25%
	White	296 97.37% (0 to 0)	295 97.04% (0 to 0)	294 96.71% (0 to 0)	289 95.38% (0 to 0)	1174 96.63%
	More than one race	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	1 0.08%
	Unknown or Not Reported	4 1.32% (0 to 0)	5 1.64% (0 to 0)	3 0.99% (0 to 0)	6 1.98% (0 to 0)	18 1.48%
		[1] Measure Description: SAF population used for analysis.				
Baseline National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1] Mean (Standard Deviation)	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Unit of measure: scores on a scale		71.7 (0 to 0)	70.4 (0 to 0)	71.1 (0 to 0)	69.5 (0 to 0)	70.7 (17.11)
		[1] Measure Description: SAF population used for analysis. The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.				
Baseline Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.52 (0 to 0)	6.59 (0 to 0)	6.49 (0 to 0)	6.56 (0 to 0)	6.54 (4.968)
		[1] Measure Description: SAF population used for analysis.				
Baseline Lesion Type [1] Measure type: Number Unit of measure: patients	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Occult		115 (0 to 0)	110 (0 to 0)	123 (0 to 0)	118 (0 to 0)	466 38.35%
Minimally Classic		101 (0 to 0)	105 (0 to 0)	97 (0 to 0)	112 (0 to 0)	415 34.16%
Predominantly Classic		82 (0 to 0)	87 (0 to 0)	82 (0 to 0)	71 (0 to 0)	322 26.5%
Missing		6 (0 to 0)	2 (0 to 0)	2 (0 to 0)	2 (0 to 0)	12 0.99%
		[1] Measure Description: SAF population used for analysis.				
Baseline Total Lesion Size [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.99 (0 to 0)	6.98 (0 to 0)	6.96 (0 to 0)	6.88 (0 to 0)	6.95 (5.202)

		Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
		[1] Measure Description: SAF population used for analysis.				
Baseline Best Corrected Visual Acuity (BCVA) [1] Mean (Standard Deviation) Unit of measure: letters read	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
		54.0 (0 to 0)	55.2 (0 to 0)	55.5 (0 to 0)	55.7 (0 to 0)	55.1 (13.14)
		[1] Measure Description: SAF population used for analysis. BCVA assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) chart. For BCVA tested via the 4 meter ETDRS protocol, 83 letters or more would represent 20/20 vision or better which would be considered an excellent outcome. Although, the ETDRS charts include 100 letters as the maximum possible score. The worst outcome is 0 letters read.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Defined "maintenance of vision" as patients who lost fewer than 15 letters in Early Treatment Diabetic Retinopathy Study (ETDRS) letter score compared to baseline.
Time Frame	Baseline and at week 52

Analysis Population Description

PPS population used for analysis.

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	269	285	270	265	1089
Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: percentage of patients	94.4 (0)	95.1 (0)	95.9 (0)	95.1 (0)	95.1 (0)

Statistical Analysis 1 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.4 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A positive value favors IAI 2.0Q4. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 2 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI (EYLEA, VEGF Trap-Eye).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.5
	Confidence Interval	(2-sided) 95.1% -5.1 to 2.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A negative value favors the IAI 0.5Q4 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 3 for Percentage of Patients Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of patients with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of patients with maintained vision for each of the groups treated with IAI (EYLEA, VEGF Trap-Eye).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.5 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus IAI. A negative value favors the IAI 2.0Q8 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	8.1 (15.25)	10.9 (13.77)	6.9 (13.41)	7.9 (15.00)	8.5 (14.44)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0054
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	3.15
	Confidence Interval	(2-sided) 95.1% 0.92 to 5.37
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4793
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.80
	Confidence Interval	(2-sided) 95.1% -3.03 to 1.43
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8179
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares Means
	Estimated Value	0.26
	Confidence Interval	(2-sided) 95.1% -1.97 to 2.49
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q8.

3. Secondary Outcome Measure:

Measure Title	Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF. Measure Type: Number Unit of Measure: percentage of patients	30.9 (0)	37.5 (0)	24.9 (0)	30.6 (0)	31.1 (0)

Statistical Analysis 1 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1042
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	6.6
	Confidence Interval	(2-sided) 95.1% -1.0 to 14.1
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1037
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-6.0
	Confidence Interval	(2-sided) 95.1% -13.2 to 1.2
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Percentage of Patients Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.93
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.4
	Confidence Interval	(2-sided) 95.1% -7.7 to 7.0
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q8.

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.
Time Frame	Baseline and at Week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: scores on a scale	4.9 (14.01)	6.7 (13.50)	4.5 (11.87)	5.1 (14.74)	5.3 (13.59)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2090
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences Least Squares means
	Estimated Value	1.28
	Confidence Interval	(2-sided) 95.1% -0.73 to 3.28
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5128
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.67
	Confidence Interval	(2-sided) 95.1% -2.69 to 1.35
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5579
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.60
	Confidence Interval	(2-sided) 95.1% -2.61 to 1.42
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A positive value favors IAI 2.0Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)
Measure Description	CNV area values measured in square millimeters (mm^2); lower values represent better outcomes.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.

IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.2 (5.59)	-4.6 (5.47)	-3.5 (5.27)	-3.4 (6.02)	-3.9 (5.61)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3575
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.33
	Confidence Interval	(2-sided) 95.1% -1.04 to 0.38
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 2.0Q4

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0507
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.71
	Confidence Interval	(2-sided) 95.1% -0.01 to 1.42
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 0.5Q4

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0173
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.86
	Confidence Interval	(2-sided) 95.1% 0.15 to 1.58
	Estimation Comments	The difference is calculated as IAI minus ranibizumab. A negative value favors IAI 2.0Q8

Reported Adverse Events

Time Frame	AEs reported from Day 1 to Wk 96. Yr 1 of tx (Day 1 to Wk 52): 21-day screening period followed by administration of study drug every 4 or 8 wks including sham injections at interim study visits (when study drug was not administered) for 48 wks.
Adverse Event Reporting Description	Yr 2 of tx (Wk 52 to Wk 96): Pts evaluated every 4 wks and received IVT injections of study drug (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 wks.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Patients received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of ranibizumab (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.

IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Patients received a 0.5mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 4 weeks for the first year. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.
IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8	Patients received a 2.0mg dose of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits. During the second year of treatment, patients were evaluated every 4 weeks and received IVT injections of Intravitreal Aflibercept Injection (IAI, EYLEA, VEGF Trap-Eye) (sham injections were not given) at intervals determined by specific re-treatment criteria. During this period, injections were given as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	94/304 (30.92%)	70/304 (23.03%)	88/304 (28.95%)	90/303 (29.7%)
Blood and lymphatic system disorders				
ANAEMIA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
COAGULOPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Congenital, familial and genetic disorders				

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ARTERIOVENOUS MALFORMATION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Ear and labyrinth disorders				
ACUTE CORONARY SYNDROME [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
ACUTE MYOCARDIAL INFARCTION [A*]	1/304 (0.33%)	2/304 (0.66%)	2/304 (0.66%)	1/303 (0.33%)
ANGINA UNSTABLE [A*]	3/304 (0.99%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
AORTIC VALVE STENOSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ARRHYTHMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ARTERIOSCLEROSIS CORONARY ARTERY [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ATRIAL FIBRILLATION [A*]	3/304 (0.99%)	2/304 (0.66%)	7/304 (2.3%)	7/303 (2.31%)
ATRIOVENTRICULAR BLOCK FIRST DEGREE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BRADYCARDIA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CARDIAC ARREST [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
CARDIAC FAILURE ACUTE [A*]	1/304 (0.33%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
CARDIAC FAILURE CHRONIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CARDIAC FAILURE CONGESTIVE [A*]	4/304 (1.32%)	2/304 (0.66%)	4/304 (1.32%)	8/303 (2.64%)
CARDIO-RESPIRATORY ARREST [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CARDIOMYOPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CORONARY ARTERY DISEASE [A*]	5/304 (1.64%)	0/304 (0%)	6/304 (1.97%)	1/303 (0.33%)
CORONARY ARTERY OCCLUSION [A*]	1/304 (0.33%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
CORONARY ARTERY STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
INTRACARDIAC THROMBUS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MENIERE'S DISEASE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MITRAL VALVE INCOMPETENCE [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
MYOCARDIAL INFARCTION [A*]	6/304 (1.97%)	1/304 (0.33%)	5/304 (1.64%)	2/303 (0.66%)
MYOCARDIAL ISCHAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PERICARDIAL EFFUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SICK SINUS SYNDROME [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUPRAVENTRICULAR TACHYCARDIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TACHYARRHYTHMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
TACHYCARDIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
VENTRICULAR FIBRILLATION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VENTRICULAR TACHYCARDIA [A*]	0/304 (0%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
VERTIGO [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
Eye disorders				
AGE-RELATED MACULAR DEGENERATION [A [1]*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ANGLE CLOSURE GLAUCOMA A [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BLEPHARITIS A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BLINDNESS TRANSIENT A [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CATARACT A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOROIDAL HAEMORRHAGE A [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOROIDAL NEOVASCULARISATION A [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONJUNCTIVAL HAEMORRHAGE A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONJUNCTIVITIS A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DRY Eye disorders A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders IRRITATION A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders PAIN A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Eye disorders PRURITUS A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOREIGN BODY SENSATION IN Eye disordersS A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
KERATITIS A [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LACRIMATION INCREASED A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MACULAR DEGENERATION A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MACULAR HOLE A [2]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MACULOPATHY A [1]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
POSTERIOR CAPSULE OPACIFICATION [A] [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PSEUDOENDOPHTHALMITIS [A] [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL DEGENERATION [A] [2]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RETINAL DETACHMENT [A] [1]*	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
RETINAL HAEMORRHAGE [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL OEDEMA [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL PIGMENT EPITHELIAL TEar and labyrinth disorders [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL PIGMENT EPITHELIOPATHY [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL TEar and labyrinth disorders [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
UVEITIS [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
VISION BLURRED [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VISUAL ACUITY REDUCED [A] [1]*	1/304 (0.33%)	1/304 (0.33%)	3/304 (0.99%)	0/303 (0%)
VITREOUS DETACHMENT [A] [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VITREOUS FLOATERS [A] [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
VITREOUS HAEMORRHAGE [A] [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Gastrointestinal disorders				
ABDOMINAL HERNIA [A]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ABDOMINAL HERNIA OBSTRUCTIVE [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
ASTHENIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CATHETER SITE HAEMATOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CHEST PAIN [A*]	2/304 (0.66%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
COLITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
COLITIS ISCHAEMIC [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
COLONIC POLYP [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONSTIPATION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DEATH [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
DEVICE DISLOCATION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
DIARRHOEA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DRUG WITHDRAWAL SYNDROME [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DUODENAL ULCER HAEMORRHAGE [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DYSPHAGIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOOD POISONING [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
GASTRIC HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTRIC ULCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS EROSIVE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
GASTROINTESTINAL DISORDER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
GASTROINTESTINAL MOTILITY DISORDER [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROINTESTINAL OBSTRUCTION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
GASTROOESOPHAGEAL REFLUX DISEASE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMATOCHEZIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMORRHOIDS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HIATUS HERNIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ILEUS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
INGUINAL HERNIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INTESTINAL OBSTRUCTION [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
LOWER GASTROINTESTINAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
NAUSEA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
NON-CARDIAC CHEST PAIN [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
OESOPHAGEAL ULCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PANCREATITIS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
PYREXIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SMALL INTESTINAL OBSTRUCTION [A*]	2/304 (0.66%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
Hepatobiliary disorders				
BILE DUCT STONE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CHOLANGITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHOLECYSTITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
CHOLECYSTITIS ACUTE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOLECYSTITIS CHRONIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHOLELITHIASIS [A*]	1/304 (0.33%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
PORTAL HYPERTENSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PORTAL VEIN THROMBOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Immune system disorders				
DRUG HYPERSENSITIVITY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Infections and infestations				
ANAL ABSCESS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ANORECTAL CELLULITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ARTHRITIS BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
BACTERIAL DISEASE CARRIER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BRONCHITIS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	3/303 (0.99%)
CELLULITIS [A*]	3/304 (0.99%)	3/304 (0.99%)	2/304 (0.66%)	0/303 (0%)
CLOSTRIDIAL Infections and infestationsION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
CLOSTRIDIUM DIFFICILE COLITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DEVICE RELATED Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
DIVERTICULITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
ENCEPHALITIS VIRAL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOCARDITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOPHTHALMITIS [A [1]*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ESCHERICHIA URINARY TRACT Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROENTERITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
GASTROENTERITIS VIRAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
INFLUENZA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
KLEBSIELLA BACTERAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LABYRINTHITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LOBAR PNEUMONIA [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
LUNG Infections and infestationsION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
NASOPHARYNGITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PHARYNGITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PNEUMONIA [A*]	14/304 (4.61%)	6/304 (1.97%)	5/304 (1.64%)	8/303 (2.64%)
PYELONEPHRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SCROTAL ABSCESS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SEPSIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SEPTIC SHOCK [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SINUSITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SINUSITIS FUNGAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
STAPHYLOCOCCAL BACTERAEMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
UPPER RESPIRATORY TRACT Infections and infestationsION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
URINARY TRACT Infections and infestationsION [A*]	1/304 (0.33%)	3/304 (0.99%)	0/304 (0%)	0/303 (0%)
URINARY TRACT Infections and infestationsION BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
URINARY TRACT Infections and infestationsION STAPHYLOCOCCAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
UROSEPSIS [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
VESTIBULAR NEURONITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL Infections and infestationsION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL PERICARDITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
WOUND Infections and infestationsION BACTERIAL [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Injury, poisoning and procedural complications				
ACCIDENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CERVICAL VERTEBRAL FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONCUSSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
FALL [A*]	8/304 (2.63%)	13/304 (4.28%)	7/304 (2.3%)	16/303 (5.28%)
FEMORAL NECK FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
FEMUR FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	2/303 (0.66%)
FIBULA FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
FOOT FRACTURE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
HEAD Injury, poisoning and procedural complications [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HIP FRACTURE [A*]	1/304 (0.33%)	4/304 (1.32%)	2/304 (0.66%)	1/303 (0.33%)
HUMERUS FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	3/304 (0.99%)	0/303 (0%)
INCISIONAL HERNIA, OBSTRUCTIVE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INCORRECT DOSE ADMINISTERED [A [2]*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
JOINT DISLOCATION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
JOINT Injury, poisoning and procedural complications [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LUMBAR VERTEBRAL FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MENISCUS LESION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
POST LAMINECTOMY SYNDROME [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PROCEDURAL PAIN [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PUBIS FRACTURE [A*]	1/304 (0.33%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
RIB FRACTURE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
ROAD TRAFFIC ACCIDENT [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SNAKE BITE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SPINAL COMPRESSION FRACTURE [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
SPINAL FRACTURE [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
STERNAL FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SUBCUTANEOUS HAEMATOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUBDURAL HAEMATOMA [A*]	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
TIBIA FRACTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
TRAUMATIC BRAIN Injury, poisoning and procedural complications [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
UPPER LIMB FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
VASCULAR PSEUDOANEURYSM [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Investigations				
Blood and lymphatic system disorders GLUCOSE INCREASED [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Blood and lymphatic system disorders PRESSURE INCREASED [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
Blood and lymphatic system disorders PRESSURE ORTHOSTATIC ABNORMAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
INTRAOCULAR PRESSURE INCREASED [A [1]*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Metabolism and nutrition disorders				
DEHYDRATION [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
DIABETES MELLITUS [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
DIABETES MELLITUS INADEQUATE CONTROL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ELECTROLYTE IMBALANCE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPERKALAEMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HYPOGLYCAEMIA [A*]	0/304 (0%)	2/304 (0.66%)	1/304 (0.33%)	0/303 (0%)
HYPOKALAEMIA [A*]	2/304 (0.66%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPONATRAEMIA [A*]	2/304 (0.66%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
MALNUTRITION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HYPOGLYCAEMIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ARTHRITIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
ARTHROPATHY [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BACK PAIN [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CERVICAL SPINAL STENOSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
INTERVERTEBRAL DISC DEGENERATION [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
INTERVERTEBRAL DISC PROTRUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUMBAR SPINAL STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
OSTEOARTHRITIS [A*]	4/304 (1.32%)	1/304 (0.33%)	3/304 (0.99%)	1/303 (0.33%)
OSTEONECROSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PAIN IN EXTREMITY [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RHABDOMYOLYSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SPINAL COLUMN STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPINAL OSTEOARTHRITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPONDYLOLISTHESIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
ATYPICAL FIBROXANTHOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
B-CELL LYMPHOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BASAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BLADDER TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	2/304 (0.66%)	1/303 (0.33%)
BLADDER TRANSITIONAL CELL CARCINOMA RECURRENT [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BRAIN NEOPLASM [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
BREAST Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	2/303 (0.66%)
BREAST Neoplasms benign, malignant and unspecified (incl cysts and polyps) IN SITU [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
BRONCHIOLOALVEOLAR CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CARDIAC MYXOMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CHRONIC LYMPHOCYTIC LEUKAEMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
COLON Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
COLON Neoplasms benign, malignant and unspecified (incl cysts and polyps) RECURRENT [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOMETRIAL Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
HEPATIC NEOPLASM MALIGNANT [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HEPATIC Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LEUKAEMIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
LUNG NEOPLASM [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUNG NEOPLASM MALIGNANT [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
LUNG SQUAMOUS CELL CARCINOMA STAGE II [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MALIGNANT MELANOMA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTASES TO CENTRAL NERVOUS SYSTEM [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
METASTASES TO Hepatobiliary disorders [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTASES TO LUNG [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
METASTASES TO LYMPH NODES [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
METASTATIC NEOPLASM [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
NEOPLASM MALIGNANT [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
NON-SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
NON-SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) STAGE IV [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
OESOPHAGEAL ADENOCARCINOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
PROSTATE Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	1/304 (0.33%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
PROSTATE Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
RECTAL Neoplasms benign, malignant and unspecified (incl cysts and polyps) STAGE III [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
RECTOSIGMOID Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RENAL CELL CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
SALIVARY GLAND Neoplasms benign, malignant and unspecified (incl cysts and polyps) RECURRENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SMALL CELL LUNG Neoplasms benign, malignant and unspecified (incl cysts and polyps) METASTATIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SMALL CELL LUNG Neoplasms benign,malignant & unspecified(incl cysts and polyps)STAGE UNSPECIFIED [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SQUAMOUS CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SQUAMOUS CELL CARCINOMA OF Skin and subcutaneous tissue disorders [A*]	5/304 (1.64%)	3/304 (0.99%)	2/304 (0.66%)	4/303 (1.32%)
THYROID Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TONGUE NEOPLASM MALIGNANT STAGE UNSPECIFIED [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TONSIL Neoplasms benign, malignant and unspecified (incl cysts and polyps) [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TUMOUR HAEMORRHAGE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
WALDENSTROM'S MACROGLOBULINAEMIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Nervous system disorders				
APHASIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BALANCE DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CAROTID ARTERY DISEASE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CAROTID ARTERY STENOSIS [A*]	0/304 (0%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
CEREBELLAR INFARCTION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CEREBRAL ARTERY THROMBOSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CEREBRAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBRAL INFARCTION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBROVASCULAR ACCIDENT [A*]	2/304 (0.66%)	3/304 (0.99%)	1/304 (0.33%)	5/303 (1.65%)
COMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONVULSION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DEMENTIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DIZZINESS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
EMBOLIC STROKE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HEADACHE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ISCHAEMIC CEREBRAL INFARCTION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LACUNAR INFARCTION [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LOSS OF CONSCIOUSNESS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
METABOLIC ENCEPHALOPATHY [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PRESYNCOPE [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
SPINAL CORD COMPRESSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SUBARACHNOID HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
SYNCOPE [A*]	3/304 (0.99%)	1/304 (0.33%)	3/304 (0.99%)	1/303 (0.33%)
TRANSIENT GLOBAL AMNESIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
TRANSIENT ISCHAEMIC ATTACK [A*]	0/304 (0%)	3/304 (0.99%)	7/304 (2.3%)	5/303 (1.65%)
Psychiatric disorders				
CONFUSIONAL STATE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MENTAL STATUS CHANGES [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Psychiatric disordersOTIC DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Renal and urinary disorders				
CALCULUS BLADDER [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CALCULUS URETERIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HAEMATURIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HYDRONEPHROSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RENAL FAILURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RENAL FAILURE ACUTE [A*]	0/304 (0%)	3/304 (0.99%)	2/304 (0.66%)	2/303 (0.66%)
RENAL FAILURE CHRONIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Reproductive system and breast disorders				
CYSTOCELE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RECTOCELE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Respiratory, thoracic and mediastinal disorders				
ACUTE RESPIRATORY FAILURE [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
APNOEIC ATTACK [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ASTHMA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A*]	3/304 (0.99%)	3/304 (0.99%)	6/304 (1.97%)	6/303 (1.98%)
COUGH [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
DYSPNOEA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
EMPHYSEMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PLEURAL EFFUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PNEUMONIA ASPIRATION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
PNEUMONITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
PULMONARY EMBOLISM [A*]	0/304 (0%)	2/304 (0.66%)	1/304 (0.33%)	2/303 (0.66%)
PULMONARY FIBROSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PULMONARY MASS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PULMONARY OEDEMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RESPIRATORY DISTRESS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RESPIRATORY FAILURE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RESTRICTIVE PULMONARY DISEASE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TRACHEAL MASS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Skin and subcutaneous tissue disorders				
ANGIOEDEMA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
Surgical and medical procedures				
CHOLECYSTECTOMY [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
MICROGRAPHIC Skin and subcutaneous tissue disorders SURGERY [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
Vascular disorders				
AORTIC ANEURYSM [A*]	1/304 (0.33%)	2/304 (0.66%)	1/304 (0.33%)	0/303 (0%)
AORTIC ANEURYSM RUPTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
AORTIC STENOSIS [A*]	1/304 (0.33%)	1/304 (0.33%)	2/304 (0.66%)	1/303 (0.33%)
ARTERIOSCLEROSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DEEP VEIN THROMBOSIS [A*]	1/304 (0.33%)	1/304 (0.33%)	1/304 (0.33%)	2/303 (0.66%)
FEMORAL ARTERY ANEURYSM [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HAEMATOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPERTENSION [A*]	2/304 (0.66%)	0/304 (0%)	3/304 (0.99%)	0/303 (0%)
HYPOTENSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ILIAC ARTERY OCCLUSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
LYMPHATIC FISTULA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LYMPHOCELE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ORTHOSTATIC HYPOTENSION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PERIPHERAL ARTERY ANEURYSM [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PERIPHERAL VASCULAR DISORDER [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PHLEBITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
PHLEBITIS DEEP A*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HAEMORRHAGIC A*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, Medra Version 14.0

[1] Ocular Fellow Eye disorders

[2] Ocular Study Eye disorders

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	261/304 (85.86%)	254/304 (83.55%)	262/304 (86.18%)	258/303 (85.15%)
Ear and labyrinth disorders				
ATRIOVENTRICULAR BLOCK FIRST DEGREE A*	16/304 (5.26%)	18/304 (5.92%)	8/304 (2.63%)	9/303 (2.97%)
Eye disorders				
AGE-RELATED MACULAR DEGENERATION A [1]*	21/304 (6.91%)	16/304 (5.26%)	12/304 (3.95%)	15/303 (4.95%)
BLEPHARITIS A [1]*	16/304 (5.26%)	18/304 (5.92%)	14/304 (4.61%)	14/303 (4.62%)
CATARACT A [1]*	10/304 (3.29%)	17/304 (5.59%)	10/304 (3.29%)	10/303 (3.3%)
CHOROIDAL NEOVASCULARISATION A [1]*	17/304 (5.59%)	10/304 (3.29%)	13/304 (4.28%)	9/303 (2.97%)
CONJUNCTIVAL HAEMORRHAGE A [1]*	16/304 (5.26%)	17/304 (5.59%)	16/304 (5.26%)	19/303 (6.27%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
DRY Eye disorders [A] [2]*	12/304 (3.95%)	16/304 (5.26%)	10/304 (3.29%)	14/303 (4.62%)
Eye disorders IRRITATION [A] [2]*	19/304 (6.25%)	13/304 (4.28%)	15/304 (4.93%)	16/303 (5.28%)
Eye disorders PAIN [A] [2]*	34/304 (11.18%)	39/304 (12.83%)	35/304 (11.51%)	31/303 (10.23%)
Eye disorders PRURITUS [A] [2]*	11/304 (3.62%)	16/304 (5.26%)	10/304 (3.29%)	6/303 (1.98%)
FOREIGN BODY SENSATION IN Eye disordersS [A] [2]*	9/304 (2.96%)	10/304 (3.29%)	10/304 (3.29%)	19/303 (6.27%)
LACRIMATION INCREASED [A] [2]*	11/304 (3.62%)	11/304 (3.62%)	15/304 (4.93%)	16/303 (5.28%)
MACULAR DEGENERATION [A] [1]*	22/304 (7.24%)	14/304 (4.61%)	21/304 (6.91%)	14/303 (4.62%)
RETINAL HAEMORRHAGE [A] [1]*	43/304 (14.14%)	36/304 (11.84%)	36/304 (11.84%)	22/303 (7.26%)
RETINAL OEDEMA [A] [1]*	18/304 (5.92%)	8/304 (2.63%)	12/304 (3.95%)	11/303 (3.63%)
RETINAL PIGMENT EPITHELIOPATHY [A] [2]*	14/304 (4.61%)	18/304 (5.92%)	17/304 (5.59%)	14/303 (4.62%)
VISION BLURRED [A] [2]*	12/304 (3.95%)	18/304 (5.92%)	17/304 (5.59%)	13/303 (4.29%)
VISUAL ACUITY REDUCED [A] [1]*	27/304 (8.88%)	10/304 (3.29%)	20/304 (6.58%)	19/303 (6.27%)
VITREOUS DETACHMENT [A] [1]*	16/304 (5.26%)	24/304 (7.89%)	25/304 (8.22%)	24/303 (7.92%)
VITREOUS FLOATERS [A] [2]*	47/304 (15.46%)	49/304 (16.12%)	30/304 (9.87%)	29/303 (9.57%)
Gastrointestinal disorders				
DIARRHOEA [A]*	18/304 (5.92%)	18/304 (5.92%)	8/304 (2.63%)	9/303 (2.97%)
NAUSEA [A]*	15/304 (4.93%)	16/304 (5.26%)	15/304 (4.93%)	15/303 (4.95%)
Infections and infestations				
BRONCHITIS [A]*	23/304 (7.57%)	19/304 (6.25%)	16/304 (5.26%)	24/303 (7.92%)
NASOPHARYNGITIS [A]*	36/304 (11.84%)	46/304 (15.13%)	41/304 (13.49%)	39/303 (12.87%)

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
SINUSITIS [A*]	18/304 (5.92%)	13/304 (4.28%)	17/304 (5.59%)	14/303 (4.62%)
UPPER RESPIRATORY TRACT Infections and infestationsION [A*]	18/304 (5.92%)	18/304 (5.92%)	19/304 (6.25%)	26/303 (8.58%)
URINARY TRACT Infections and infestationsION [A*]	26/304 (8.55%)	22/304 (7.24%)	25/304 (8.22%)	23/303 (7.59%)
Injury, poisoning and procedural complications				
FALL [A*]	19/304 (6.25%)	13/304 (4.28%)	15/304 (4.93%)	21/303 (6.93%)
Investigations				
Blood and lymphatic system disorders GLUCOSE INCREASED [A*]	13/304 (4.28%)	12/304 (3.95%)	17/304 (5.59%)	16/303 (5.28%)
INTRAOCULAR PRESSURE INCREASED [A [1]*]	16/304 (5.26%)	8/304 (2.63%)	15/304 (4.93%)	15/303 (4.95%)
Musculoskeletal and connective tissue disorders				
ARTHRALGIA [A*]	17/304 (5.59%)	18/304 (5.92%)	17/304 (5.59%)	8/303 (2.64%)
BACK PAIN [A*]	11/304 (3.62%)	14/304 (4.61%)	13/304 (4.28%)	16/303 (5.28%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
BASAL CELL CARCINOMA [A*]	5/304 (1.64%)	11/304 (3.62%)	15/304 (4.93%)	17/303 (5.61%)
Nervous system disorders				
HEADACHE [A*]	21/304 (6.91%)	14/304 (4.61%)	16/304 (5.26%)	15/303 (4.95%)
Respiratory, thoracic and mediastinal disorders				
COUGH [A*]	16/304 (5.26%)	13/304 (4.28%)	10/304 (3.29%)	13/303 (4.29%)
Vascular disorders				

	Ranibizumab 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q4	IAI (EYLEA, VEGF Trap-Eye) 0.5mg Q4	IAI (EYLEA, VEGF Trap-Eye) 2.0mg Q8
HYPERTENSION [A*]	35/304 (11.51%)	30/304 (9.87%)	32/304 (10.53%)	33/303 (10.89%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, Medra Version 14.0

[1] Ocular Fellow Eye disorders

[2] Ocular Study Eye disorders

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals
Phone:
Email: clinicaltrials@regeneron.com

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Samsung Bioepis Exhibit 1017, pg. 1661

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Latest version (submitted December 20, 2012) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	July 31, 2007	None (earliest Version on record)
2	○	○	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

Version	A	B	Submitted Date	Changes
3	○	○	November 14, 2007	Contacts/Locations and Study Status
4	○	○	December 4, 2007	Study Status and Contacts/Locations
5	○	○	March 13, 2008	Study Status and Eligibility
6	○	○	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures and Study Identification
7	○	○	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	○	○	March 3, 2009	Study Status and Contacts/Locations
9	○	○	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Identification
10	○	○	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	○	○	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	○	○	January 5, 2011	Study Status
13	○	○	April 18, 2011	Study Status, Study Design
14	○	○	May 4, 2011	Study Status
15	○	○	December 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators
16	◉	◉	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	○	○	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow, More Information and Study Status
18	○	○	December 20, 2012	More Information, Outcome Measures, References and Study Status

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00509795

Submitted Date: April 13, 2012 (v16)

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Vascular Endothelial Growth Factor VEGF Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-Related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2012

Overall Status: Completed

Study Start: August 2007

Primary Completion: September 2010 [Actual]

Study Completion: July 2011 [Actual]

First Submitted: July 31, 2007

First Submitted that Met QC Criteria: July 31, 2007

First Posted: August 1, 2007 [Estimate]

Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	April 13, 2012
Results First Posted:	April 16, 2012 [Estimate]
Certification/Extension First Submitted:	January 5, 2011
Certification/Extension First Submitted that Met QC Criteria:	January 5, 2011
Certification/Extension First Posted:	January 10, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	April 13, 2012
Last Update Posted:	April 16, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase 3, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in the US and Canada.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1217 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: ranibizumab 0.5mg Q4	Biological: ranibizumab Participants received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • Lucentis

Arms	Assigned Interventions
Experimental: aflibercept injection 2.0mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 0.5mg Q4	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 0.5mg dose of aflibercept injection every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321
Experimental: aflibercept injection 2.0mg Q8	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321) Participants received a 2.0mg dose of aflibercept injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks. Other Names: • VEGF Trap-Eye • BAY86-5321

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed Informed Consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. Early Treatment Diabetic Retinopathy Study (ETDRS) Best Corrected Visual Acuity (BCVA) of: letter score of 73 to 25 (20/40 to 20/320) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member. See Appendix J.4) understand and willing to sign the informed consent form.

Key

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD except dietary supplements or vitamins.
2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye, except dietary supplements or vitamins.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size > 12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.

5. Subretinal hemorrhage that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye. (If the blood is under the fovea, then the fovea must be surrounded 270 degrees by visible CNV.)
6. Scar or fibrosis, making up > 50% of total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any other vascular disease affecting the retina,other than AMD, in either eye.
12. Prior vitrectomy in the study eye.
13. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
14. Any history of macular hole of stage 2 and above in the study eye.
15. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of day 1, as long as its unlikely to interfere with the injection.

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Alabama**

Birmingham, Alabama, United States, 35205

Birmingham, Alabama, United States, 35223

United States, Arizona

Phoenix, Arizona, United States, 85014

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

Tucson, Arizona, United States, 85710

United States, California

Beverly Hills, California, United States, 90211

Campbell, California, United States, 95008

Fullerton, California, United States, 92835

Glendale, California, United States, 91203

Irvine, California, United States, 92697

La Jolla, California, United States, 92037

Loma Linda, California, United States, 92354

Los Angeles, California, United States, 90033

Los Angeles, California, United States, 90048

Menlo Park, California, United States, 94025

Mountain View, California, United States, 94040

Oakland, California, United States, 94609

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Sacramento, California, United States, 95819

San Diego, California, United States, 92120

San Francisco, California, United States, 94107

Santa Ana, California, United States, 92705

Torrance, California, United States, 90503

Ventura, California, United States, 93003

Westlake Village, California, United States, 91361

Yorba Linda, California, United States, 92887

United States, Colorado

Aurora, Colorado, United States, 80045

Denver, Colorado, United States, 80205

Denver, Colorado, United States, 80230

United States, Connecticut

Bridgeport, Connecticut, United States, 06606

Hamden, Connecticut, United States, 06518

New Haven, Connecticut, United States, 06510

New London, Connecticut, United States, 06320

United States, Florida

Altamonte Springs, Florida, United States, 32701

Boynton Beach, Florida, United States, 33426

Fort Myers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33351

Ft. Myers, Florida, United States, 33912

Gainesville, Florida, United States, 32610

Jacksonville, Florida, United States, 32224

Miami, Florida, United States, 33136

Miami, Florida, United States, 33143

Mount Dora, Florida, United States, 32757

Orlando, Florida, United States, 32803

Orlando, Florida, United States, 32806

Oscala, Florida, United States, 34472

Palm Beach Gardens, Florida, United States, 33410

Pensacola, Florida, United States, 32503

Sarasota, Florida, United States

Stuart, Florida, United States, 34994

Tampa, Florida, United States, 33612

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Aiea, Hawaii, United States, 96701

Honolulu, Hawaii, United States, 96813

United States, Illinois

Oak Brook, Illinois, United States, 60523

United States, Indiana

Fort Wayne, Indiana, United States, 46804

Indianapolis, Indiana, United States, 46202

Indianapolis, Indiana, United States, 46260

Indianapolis, Indiana, United States, 46280

New Albany, Indiana, United States, 47150

United States, Iowa

Iowa City, Iowa, United States, 52242-1091

United States, Kansas

Wichita, Kansas, United States, 67214

United States, Kentucky

Louisville, Kentucky, United States, 40202

Louisville, Kentucky, United States, 40207

Paducah, Kentucky, United States, 42001

United States, Louisiana

New Orleans, Louisiana, United States, 70115

New Orleans, Louisiana, United States, 70121

Shreveport, Louisiana, United States, 71105

United States, Maine

Bangor, Maine, United States, 04401

Portland, Maine, United States, 04102

United States, Maryland

Baltimore, Maryland, United States, 21209

Baltimore, Maryland, United States, 21287

Chevy Chase, Maryland, United States, 20815

Hagerstown, Maryland, United States, 21740

Towson, Maryland, United States, 21204

United States, Massachusetts

Boston, Massachusetts, United States, 02111

Boston, Massachusetts, United States, 02114

Boston, Massachusetts, United States, 02215

Boston, Massachusetts, United States

Peabody, Massachusetts, United States, 01960

United States, Michigan

Ann Arbor, Michigan, United States, 48105

Battle Creek, Michigan, United States, 49015

Detroit, Michigan, United States, 48202

Grand Rapids, Michigan, United States, 49525

Jackson, Michigan, United States, 49201

Royal Oak, Michigan, United States, 48073

Southfield, Michigan, United States, 48034

West Bloomfield, Michigan, United States, 48322

United States, Minnesota

Edina, Minnesota, United States, 55435

Minneapolis, Minnesota, United States, 55404

Rochester, Minnesota, United States, 55905

United States, Missouri

Florissant, Missouri, United States, 63031

Kansas City, Missouri, United States, 64108

Kansas City, Missouri, United States, 64111

Springfield, Missouri, United States, 65804

St. Louis, Missouri, United States, 63110

United States, Montana

Missoula, Montana, United States, 59801

United States, Nebraska

Lincoln, Nebraska, United States, 68506

Omaha, Nebraska, United States, 68131

United States, Nevada

Las Vegas, Nevada, United States, 89144

United States, New Jersey

Lawrenceville, New Jersey, United States, 08648

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Teaneck, New Jersey, United States, 07666

Toms River, New Jersey, United States, 08753

United States, New Mexico

Albuquerque, New Mexico, United States, 87106

United States, New York

Albany, New York, United States, 12206

Brooklyn, New York, United States, 11223

Lynbrook, New York, United States, 11563

New York, New York, United States, 10003

New York, New York, United States, 10021

New York, New York, United States, 10032

Poughkeepsie, New York, United States, 12601

Rochester, New York, United States, 14620

Rochester, New York, United States, 14642

Slingerlands, New York, United States, 12159

Syracuse, New York, United States, 13224

United States, North Carolina

Asheville, North Carolina, United States, 28803

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

Southern Pines, North Carolina, United States, 28387

Winston-Salem, North Carolina, United States, 27157

United States, Ohio

Cincinnati, Ohio, United States, 45202

Cincinnati, Ohio, United States, 45242

Columbus, Ohio, United States, 43215

Toledo, Ohio, United States, 43608

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Ashland, Oregon, United States, 97520

Portland, Oregon, United States, 97210

Portland, Oregon, United States, 97227

Salem, Oregon, United States, 97302

United States, Pennsylvania

Kingston, Pennsylvania, United States, 18704

Philadelphia, Pennsylvania, United States, 19104

Philadelphia, Pennsylvania, United States, 19107

Philadelphia, Pennsylvania, United States, 19124

Pittsberg, Pennsylvania, United States, 15231

Pittsburgh, Pennsylvania, United States, 15212

Pittsburgh, Pennsylvania, United States, 15213

West Mifflin, Pennsylvania, United States, 15122

Wyomissing, Pennsylvania, United States, 19610

United States, Rhode Island

Providence, Rhode Island, United States, 02903-4928

United States, South Carolina

Charleston, South Carolina, United States, 29414

Columbia, South Carolina, United States, 29223

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Memphis, Tennessee, United States, 38119

Memphis, Tennessee, United States, 38120

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Austin, Texas, United States, 78705

Corpus Cristi, Texas, United States, 78413

Dallas, Texas, United States, 75390

DeSoto, Texas, United States, 75115

Ft. Worth, Texas, United States, 76102

Ft. Worth, Texas, United States, 76104

Galveston, Texas, United States, 77555

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

Odessa, Texas, United States, 79761

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Salt Lake City, Utah, United States, 84132

United States, Vermont

Burlington, Vermont, United States, 05401

United States, Virginia

Charlottesville, Virginia, United States, 22908

Fairfax, Virginia, United States, 22031

Richmond, Virginia, United States, 23221

United States, Washington

Seattle, Washington, United States, 98104

Silverdale, Washington, United States, 98383

United States, Wisconsin

Madison, Wisconsin, United States, 53715

Madison, Wisconsin, United States, 58705

Milwaukee, Wisconsin, United States, 53226

Canada, Alberta

Calgary, Alberta, Canada, T3E 7MB

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 1B3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

Ottawa, Ontario, Canada, K1H8L6

Toronto, Ontario, Canada, M4N3M5

Toronto, Ontario, Canada, M5C 2T2

Canada, Quebec

Montreal, Quebec, Canada, H1T 2M4

Montreal, Quebec, Canada, H3A 1A1

Canada, Saskatchewan

Regina, Saskatchewan, Canada, S4T 1A5

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Study Results

Participant Flow

Recruitment Details	The study was conducted at 164 sites in the United States and Canada. Recruitment period: 02 Aug 2007 to 15 Sep 2009.

Pre-assignment Details	2063 participants were screened, 1217 randomized, and 1215 included in the Safety Analysis Set (SAF). The Full Analysis Set (FAS) included 1210 participants with at least 1 post-baseline assessment. The Per Protocol Set (PPS) included 1089 participants who received ≥ 9 doses of study drug and attended ≥ 9 scheduled visits during the first year.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg Q4	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 0.5mg Q4	Aflibercept Injection (VEGF Trap-Eye, BAY86-5321) 2.0mg Q8
Started	306	304	304	303
Participants Received Treatment (SAF)	304	304	304	303
Full Analysis Set (FAS) Population	304	304	301	301
Per Protocol Set (PPS) Population	269	285	270	265
Completed	284	293	277	276
Not Completed	22	11	27	27
Adverse Event	4	3	5	4
Death	3	1	2	7
Lack of Efficacy	0	0	2	2
Lost to Follow-up	1	2	4	4
OTHER	1	0	4	1
Protocol Violation	3	0	3	1
Withdrawal by Subject	10	5	7	8

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.

Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants		304	304	304	303	1215
Age Continuous [1] Mean (Standard Deviation) Unit of measure: years	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
		78.2 (0 to 0)	77.7 (0 to 0)	78.3 (0 to 0)	77.9 (0 to 0)	78.0 (8.00)
		[1] Measure Description: SAF population used for analysis.				
Sex: Female, Male [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	Female	172 56.58% (0 to 0)	194 63.82% (0 to 0)	169 55.59% (0 to 0)	179 59.08% (0 to 0)	714 58.77%
	Male	132 43.42% (0 to 0)	110 36.18% (0 to 0)	135 44.41% (0 to 0)	124 40.92% (0 to 0)	501 41.23%
		[1] Measure Description: SAF population used for analysis.				
Ethnicity (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants

		Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
	Hispanic or Latino	7 2.3% (0 to 0)	11 3.62% (0 to 0)	11 3.62% (0 to 0)	12 3.96% (0 to 0)	41 3.37%
	Not Hispanic or Latino	297 97.7% (0 to 0)	293 96.38% (0 to 0)	293 96.38% (0 to 0)	291 96.04% (0 to 0)	1174 96.63%
	Unknown or Not Reported	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	0 0%
		[1] Measure Description: SAF population used for analysis.				
Race (NIH/OMB) [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
	American Indian or Alaska Native	2 0.66% (0 to 0)	0 0% (0 to 0)	2 0.66% (0 to 0)	1 0.33% (0 to 0)	5 0.41%
	Asian	0 0% (0 to 0)	3 0.99% (0 to 0)	5 1.64% (0 to 0)	4 1.32% (0 to 0)	12 0.99%
	Native Hawaiian or Other Pacific Islander	1 0.33% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	2 0.16%
	Black or African American	1 0.33% (0 to 0)	1 0.33% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	3 0.25%
	White	296 97.37% (0 to 0)	295 97.04% (0 to 0)	294 96.71% (0 to 0)	289 95.38% (0 to 0)	1174 96.63%
	More than one race	0 0% (0 to 0)	0 0% (0 to 0)	0 0% (0 to 0)	1 0.33% (0 to 0)	1 0.08%

		Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
	Unknown or Not Reported	4 1.32% (0 to 0)	5 1.64% (0 to 0)	3 0.99% (0 to 0)	6 1.98% (0 to 0)	18 1.48%
		[1] Measure Description: SAF population used for analysis.				
Baseline National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		71.7 (0 to 0)	70.4 (0 to 0)	71.1 (0 to 0)	69.5 (0 to 0)	70.7 (17.11)
		[1] Measure Description: SAF population used for analysis. The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.				
Baseline Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.52 (0 to 0)	6.59 (0 to 0)	6.49 (0 to 0)	6.56 (0 to 0)	6.54 (4.968)
		[1] Measure Description: SAF population used for analysis.				
Baseline Lesion Type [1] Measure type: Number Unit of measure: participants	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Occult		115 (0 to 0)	110 (0 to 0)	123 (0 to 0)	118 (0 to 0)	466 38.35%

		Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Minimally Classic		101 (0 to 0)	105 (0 to 0)	97 (0 to 0)	112 (0 to 0)	415 34.16%
Predominantly Classic		82 (0 to 0)	87 (0 to 0)	82 (0 to 0)	71 (0 to 0)	322 26.5%
Missing		6 (0 to 0)	2 (0 to 0)	2 (0 to 0)	2 (0 to 0)	12 0.99%
		[1] Measure Description: SAF population used for analysis.				
Baseline Total Lesion Size [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: mm^2		6.99 (0 to 0)	6.98 (0 to 0)	6.96 (0 to 0)	6.88 (0 to 0)	6.95 (5.202)
		[1] Measure Description: SAF population used for analysis.				
Baseline Best Corrected Visual Acuity (BCVA) [1]	Number Analyzed	304 Participants	304 Participants	304 Participants	303 Participants	1215 Participants
Mean (Standard Deviation) Unit of measure: letters read		54.0 (0 to 0)	55.2 (0 to 0)	55.5 (0 to 0)	55.7 (0 to 0)	55.1 (13.14)
		[1] Measure Description: SAF population used for analysis. BCVA assessed by Early Treatment Diabetic Retinopathy Study (ETDRS) chart. For BCVA tested via the 4 meter ETDRS protocol, 83 letters or more would represent 20/20 vision or better which would be considered an excellent outcome. Although, the ETDRS charts include 100 letters as the maximum possible score. The worst outcome is 0 letters read.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Defined "maintenance of vision" as subjects who lost fewer than 15 letters in Early Treatment Diabetic Retinopathy Study (ETDRS) letter score compared to baseline.
Time Frame	Baseline and at week 52

Analysis Population Description

PPS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants Analyzed	269	285	270	265	1089
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: percentage of participants	94.4 (0)	95.1 (0)	95.9 (0)	95.1 (0)	95.1 (0)

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of subjects with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of subjects with maintained vision for each of the groups treated with VEGF-Trap Eye.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.4 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus VEGF Trap-Eye. A negative value favors the VEGF Trap-Eye 2.0Q4 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 0.5mg Q4
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of subjects with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of subjects with maintained vision for each of the groups treated with VEGF-Trap Eye.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.5
	Confidence Interval	(2-sided) 95.1% -5.1 to 2.1
	Estimation Comments	The difference is calculated as ranibizumab minus VEGF Trap-Eye. A negative value favors the VEGF Trap-Eye 0.5Q4 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q8
	Comments	The statistical approach included a conditional sequence of calculations of the 95.1% CI using normal approximation of the difference between the proportion of subjects with maintained vision at Week 52 for the group treated with 0.5 mg ranibizumab and the proportion of subjects with maintained vision for each of the groups treated with VEGF-Trap Eye.
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin was set at 10%. The power is 90% according to the sample size estimation of the study protocol. Although not in the analysis plan for the study, in a separate communication, the FDA further explained that, whereas the 10% non-inferiority margin would be used to assess non-inferiority, a 5% non-inferiority margin would be used to assess clinical equivalence.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.7
	Confidence Interval	(2-sided) 95.1% -4.5 to 3.1
	Estimation Comments	The difference is calculated as ranibizumab minus VEGF Trap-Eye. A negative value favors the VEGF Trap-Eye 2.0Q8 group. As adjustment of multiple comparisons as conditional sequence of statistical hypotheses is used with alpha = 0.049.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.

Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	8.1 (15.25)	10.9 (13.77)	6.9 (13.41)	7.9 (15.00)	8.5 (14.44)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0054
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	3.15
	Confidence Interval	(2-sided) 95.1% 0.92 to 5.37
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4793
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.80
	Confidence Interval	(2-sided) 95.1% -3.03 to 1.43
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.8179
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares Means
	Estimated Value	0.26
	Confidence Interval	(2-sided) 95.1% -1.97 to 2.49
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q8.

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.

Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF. Measure Type: Number Unit of Measure: percentage of participants	30.9 (0)	37.5 (0)	24.9 (0)	30.6 (0)	31.1 (0)

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1042
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	6.6
	Confidence Interval	(2-sided) 95.1% -1.0 to 14.1
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q4.

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 0.5mg Q4
	Comments	The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1037
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-6.0
	Confidence Interval	(2-sided) 95.1% -13.2 to 1.2
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 0.5Q4.

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF.

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q8
	Comments	The pairwise The null hypothesis is that both percentages are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.93
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.4
	Confidence Interval	(2-sided) 95.1% -7.7 to 7.0
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q8.

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The NEI VFQ-25 total score ranges from 0-100 with a score of 0 being the worst outcome and 100 being the best outcome. The NEI VFQ questionnaire is organized as a collection of subscales which are all scored from 0-100. To reach the overall composite score, each sub-scale score is averaged in order to give each sub-scale equal weight.
Time Frame	Baseline and at Week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.
Total	

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: scores on a scale	4.9 (14.01)	6.7 (13.50)	4.5 (11.87)	5.1 (14.74)	5.3 (13.59)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.2090
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences Least Squares means
	Estimated Value	1.28
	Confidence Interval	(2-sided) 95.1% -0.73 to 3.28
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5128
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.67
	Confidence Interval	(2-sided) 95.1% -2.69 to 1.35
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 0.5Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5579
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.60
	Confidence Interval	(2-sided) 95.1% -2.61 to 1.42
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A positive value favors VEGF Trap-Eye 2.0Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)
Measure Description	CNV area values measured in square millimeters (mm^2); lower values represent better outcomes.
Time Frame	Baseline and at week 52

Analysis Population Description

FAS population used for analysis.

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via IVT injection every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

Total	

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8	Total
Overall Number of Participants Analyzed	304	304	301	301	1210
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF) Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.2 (5.59)	-4.6 (5.47)	-3.5 (5.27)	-3.4 (6.02)	-3.9 (5.61)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3575
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.33
	Confidence Interval	(2-sided) 95.1% -1.04 to 0.38
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A negative value favors VEGF Trap-Eye 2.0Q4

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0507
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.71
	Confidence Interval	(2-sided) 95.1% -0.01 to 1.42
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A negative value favors VEGF Trap-Eye 0.5Q4

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection 2.0mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline measure as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0173
	Comments	As adjustment of multiple comparisons, a conditional sequence of statistical hypotheses is used with alpha = 0.049
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.86
	Confidence Interval	(2-sided) 95.1% 0.15 to 1.58
	Estimation Comments	The difference is calculated as VEGF Trap-Eye minus ranibizumab. A negative value favors VEGF Trap-Eye 2.0Q8

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a 0.5mg dose of ranibizumab via intravitreal (IVT) injection every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q4	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 0.5mg Q4	Participants received a 0.5mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 4 weeks for the first year.
Aflibercept Injection 2.0mg Q8	Participants received a 2.0mg dose of aflibercept injection (VEGF Trap-Eye, BAY86-5321) every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year and were to receive sham injections at interim monthly visits.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	68/304 (22.37%)	46/304 (15.13%)	56/304 (18.42%)	56/303 (18.48%)
Blood and lymphatic system disorders				
ANAEMIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Cardiac disorders				
ACUTE CORONARY SYNDROME [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ACUTE MYOCARDIAL INFARCTION [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
ANGINA UNSTABLE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
AORTIC VALVE STENOSIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ARRHYTHMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
ATRIAL FIBRILLATION [A*]	2/304 (0.66%)	2/304 (0.66%)	3/304 (0.99%)	3/303 (0.99%)
BRADYCARDIA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CARDIAC ARREST [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CARDIAC FAILURE CHRONIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CARDIAC FAILURE CONGESTIVE [A*]	2/304 (0.66%)	1/304 (0.33%)	2/304 (0.66%)	3/303 (0.99%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
CORONARY ARTERY DISEASE [A*]	4/304 (1.32%)	0/304 (0%)	4/304 (1.32%)	0/303 (0%)
CORONARY ARTERY OCCLUSION [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
INTRACARDIAC THROMBUS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MITRAL VALVE INCOMPETENCE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
MYOCARDIAL INFARCTION [A*]	3/304 (0.99%)	1/304 (0.33%)	3/304 (0.99%)	2/303 (0.66%)
SICK SINUS SYNDROME [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUPRAVENTRICULAR TACHYCARDIA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
TACHYCARDIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
VENTRICULAR FIBRILLATION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VENTRICULAR TACHYCARDIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Congenital, familial and genetic disorders				
ARTERIOVENOUS MALFORMATION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Ear and labyrinth disorders				
MENIERE'S DISEASE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VERTIGO [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
Eye disorders				
ANGLE CLOSURE GLAUCOMA [A [1]*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CATARACT [A [1]*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
KERATITIS A [1]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
MACULAR HOLE A [1]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
POSTERIOR CAPSULE OPACIFICATION A [2]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RETINAL DEGENERATION A [1]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RETINAL DETACHMENT A [2]*	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
RETINAL DETACHMENT A [1]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
RETINAL HAEMORRHAGE A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL HAEMORRHAGE A [1]*	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
RETINAL OEDEMA A [1]*	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
RETINAL PIGMENT EPITHELIAL TEAR A [1]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL TEAR A [2]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RETINAL TEAR A [1]*	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VISUAL ACUITY REDUCED A [2]*	2/304 (0.66%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
VISUAL ACUITY REDUCED A [1]*	2/304 (0.66%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
Gastrointestinal disorders				
COLITIS ISCHAEMIC A*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
COLONIC POLYP A*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CONSTIPATION A*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DIARRHOEA A*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DUODENAL ULCER HAEMORRHAGE A*	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
GASTRIC ULCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
GASTRITIS EROSIVE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
GASTROINTESTINAL MOTILITY DISORDER [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROOESOPHAGEAL REFLUX DISEASE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMATOCHEZIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HAEMORRHOIDS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
HIATUS HERNIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ILEUS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
INTESTINAL OBSTRUCTION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LOWER GASTROINTESTINAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
General disorders				
ASTHENIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CATHETER SITE HAEMATOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CHEST PAIN [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
DRUG WITHDRAWAL SYNDROME [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
NON-CARDIAC CHEST PAIN [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PYREXIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Hepatobiliary disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
BILE DUCT STONE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHOLECYSTITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CHOLECYSTITIS CHRONIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHOLELITHIASIS [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PORTAL VEIN THROMBOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Infections and infestations				
ARTHRITIS BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
BRONCHITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
CELLULITIS [A*]	2/304 (0.66%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
CLOSTRIDIAL INFECTION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CLOSTRIDIUM DIFFICILE COLITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DEVICE RELATED INFECTION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
DIVERTICULITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ENDOCARDITIS [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ENDOPHTHALMITIS [A [2]*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
ENDOPHTHALMITIS [A [1]*]	3/304 (0.99%)	3/304 (0.99%)	0/304 (0%)	0/303 (0%)
ESCHERICHIA URINARY TRACT INFECTION [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
GASTROENTERITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	2/303 (0.66%)
LOBAR PNEUMONIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LUNG INFECTION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
PHARYNGITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PNEUMONIA [A*]	7/304 (2.3%)	3/304 (0.99%)	2/304 (0.66%)	5/303 (1.65%)
PYELONEPHRITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SCROTAL ABSCESS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SEPTIC SHOCK [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SINUSITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SINUSITIS FUNGAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
STAPHYLOCOCCAL BACTERAEMIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
URINARY TRACT INFECTION [A*]	1/304 (0.33%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
URINARY TRACT INFECTION BACTERIAL [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VESTIBULAR NEURONITIS [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL INFECTION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
VIRAL PERICARDITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Injury, poisoning and procedural complications				
FALL [A*]	5/304 (1.64%)	6/304 (1.97%)	4/304 (1.32%)	6/303 (1.98%)
FEMUR FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HIP FRACTURE [A*]	1/304 (0.33%)	2/304 (0.66%)	2/304 (0.66%)	0/303 (0%)
HUMERUS FRACTURE [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
INCISIONAL HERNIA, OBSTRUCTIVE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
INCORRECT DOSE ADMINISTERED [A] [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LUMBAR VERTEBRAL FRACTURE [A]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PUBIS FRACTURE [A]*	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RIB FRACTURE [A]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
SNAKE BITE [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SPINAL FRACTURE [A]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SUBCUTANEOUS HAEMATOMA [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SUBDURAL HAEMATOMA [A]*	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	2/303 (0.66%)
TRAUMATIC BRAIN INJURY [A]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
UPPER LIMB FRACTURE [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Investigations				
BLOOD GLUCOSE INCREASED [A]*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
BLOOD PRESSURE INCREASED [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INTRAOCULAR PRESSURE INCREASED [A] [1]*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Metabolism and nutrition disorders				
DEHYDRATION [A]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
DIABETES MELLITUS [A]*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
DIABETES MELLITUS INADEQUATE CONTROL [A]*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
HYPERKALAEMIA [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
HYPOKALAEMIA [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HYPONATRAEMIA [A*]	1/304 (0.33%)	1/304 (0.33%)	1/304 (0.33%)	1/303 (0.33%)
MALNUTRITION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HYPOGLYCAEMIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Musculoskeletal and connective tissue disorders				
BACK PAIN [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INTERVERTEBRAL DISC DEGENERATION [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
INTERVERTEBRAL DISC PROTRUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUMBAR SPINAL STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
OSTEOARTHRITIS [A*]	3/304 (0.99%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPINAL COLUMN STENOSIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPINAL OSTEOARTHRITIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
SPONDYLOLISTHESIS [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
ATYPICAL FIBROXANTHOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
BLADDER TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	1/304 (0.33%)	0/303 (0%)
BREAST CANCER [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
BREAST CANCER IN SITU [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
BRONCHIOLOALVEOLAR CARCINOMA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CHRONIC LYMPHOCYTIC LEUKAEMIA [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
COLON CANCER [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
HEPATIC NEOPLASM MALIGNANT [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
LEUKAEMIA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
LUNG NEOPLASM [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
LUNG NEOPLASM MALIGNANT [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
MALIGNANT MELANOMA [A*]	1/304 (0.33%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
NON-SMALL CELL LUNG CANCER STAGE IV [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
OESOPHAGEAL ADENOCARCINOMA [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PROSTATE CANCER [A*]	1/304 (0.33%)	0/304 (0%)	2/304 (0.66%)	0/303 (0%)
PROSTATE CANCER METASTATIC [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
RECTOSIGMOID CANCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
RENAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
SALIVARY GLAND CANCER RECURRENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SQUAMOUS CELL CARCINOMA OF SKIN [A*]	3/304 (0.99%)	2/304 (0.66%)	1/304 (0.33%)	3/303 (0.99%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
THYROID CANCER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TONSIL CANCER [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
TRANSITIONAL CELL CARCINOMA [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
TUMOUR PERFORATION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
Nervous system disorders				
BALANCE DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
CAROTID ARTERY STENOSIS [A*]	0/304 (0%)	2/304 (0.66%)	0/304 (0%)	0/303 (0%)
CEREBRAL ARTERY THROMBOSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
CEREBRAL HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBRAL INFARCTION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
CEREBROVASCULAR ACCIDENT [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	3/303 (0.99%)
ISCHAEMIC CEREBRAL INFARCTION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
METABOLIC ENCEPHALOPATHY [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SPINAL CORD COMPRESSION [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
SUBARACHNOID HAEMORRHAGE [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
SYNCOPE [A*]	1/304 (0.33%)	1/304 (0.33%)	2/304 (0.66%)	0/303 (0%)
TRANSIENT ISCHAEMIC ATTACK [A*]	0/304 (0%)	2/304 (0.66%)	5/304 (1.64%)	1/303 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
Psychiatric disorders				
CONFUSIONAL STATE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
MENTAL STATUS CHANGES [A*]	2/304 (0.66%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PSYCHOTIC DISORDER [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Renal and urinary disorders				
CALCULUS URETERIC [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
RENAL FAILURE ACUTE [A*]	0/304 (0%)	0/304 (0%)	2/304 (0.66%)	1/303 (0.33%)
Reproductive system and breast disorders				
CYSTOCELE [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
Respiratory, thoracic and mediastinal disorders				
APNOEIC ATTACK [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
CHRONIC OBSTRUCTIVE PULMONARY DISEASE [A*]	2/304 (0.66%)	3/304 (0.99%)	2/304 (0.66%)	2/303 (0.66%)
PLEURAL EFFUSION [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
PNEUMONIA ASPIRATION [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
PNEUMONITIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	1/303 (0.33%)
PULMONARY EMBOLISM [A*]	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
PULMONARY FIBROSIS [A*]	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
RESPIRATORY FAILURE [A*]	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
Vascular disorders				
AORTIC ANEURYSM [A*]	1/304 (0.33%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
AORTIC ANEURYSM RUPTURE [A*]	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
AORTIC STENOSIS A*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
ARTERIOSCLEROSIS A*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)
DEEP VEIN THROMBOSIS A*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	1/303 (0.33%)
HYPERTENSION A*	2/304 (0.66%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ILIAC ARTERY OCCLUSION A*	0/304 (0%)	0/304 (0%)	1/304 (0.33%)	0/303 (0%)
ORTHOSTATIC HYPOTENSION A*	1/304 (0.33%)	0/304 (0%)	0/304 (0%)	0/303 (0%)
PERIPHERAL ARTERY ANEURYSM A*	0/304 (0%)	1/304 (0.33%)	0/304 (0%)	0/303 (0%)
SHOCK HAEMORRHAGIC A*	0/304 (0%)	0/304 (0%)	0/304 (0%)	1/303 (0.33%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA 13.0

[1] Study Eye

[2] Fellow Eye

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	284/304 (93.42%)	280/304 (92.11%)	278/304 (91.45%)	288/303 (95.05%)
Eye disorders				
BLEPHARITIS A [1]*	12/304 (3.95%)	16/304 (5.26%)	10/304 (3.29%)	11/303 (3.63%)
CONJUNCTIVAL HAEMORRHAGE A [2]*	144/304 (47.37%)	109/304 (35.86%)	120/304 (39.47%)	131/303 (43.23%)
EYE IRRITATION A [2]*	16/304 (5.26%)	13/304 (4.28%)	13/304 (4.28%)	12/303 (3.96%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
EYE PAIN [A] [2]*	26/304 (8.55%)	33/304 (10.86%)	27/304 (8.88%)	22/303 (7.26%)
FOREIGN BODY SENSATION IN EYES [A] [2]*	9/304 (2.96%)	8/304 (2.63%)	9/304 (2.96%)	16/303 (5.28%)
MACULAR DEGENERATION [A] [1]*	30/304 (9.87%)	19/304 (6.25%)	25/304 (8.22%)	20/303 (6.6%)
MACULAR DEGENERATION [A] [2]*	16/304 (5.26%)	16/304 (5.26%)	17/304 (5.59%)	10/303 (3.3%)
MACULOPATHY [A] [2]*	19/304 (6.25%)	10/304 (3.29%)	20/304 (6.58%)	8/303 (2.64%)
RETINAL HAEMORRHAGE [A] [1]*	28/304 (9.21%)	20/304 (6.58%)	21/304 (6.91%)	14/303 (4.62%)
RETINAL HAEMORRHAGE [A] [2]*	18/304 (5.92%)	9/304 (2.96%)	17/304 (5.59%)	21/303 (6.93%)
RETINAL PIGMENT EPITHELIOPATHY [A] [2]*	11/304 (3.62%)	16/304 (5.26%)	15/304 (4.93%)	13/303 (4.29%)
VISUAL ACUITY REDUCED [A] [2]*	18/304 (5.92%)	23/304 (7.57%)	21/304 (6.91%)	20/303 (6.6%)
VITREOUS DETACHMENT [A] [1]*	12/304 (3.95%)	16/304 (5.26%)	19/304 (6.25%)	16/303 (5.28%)
VITREOUS DETACHMENT [A] [2]*	24/304 (7.89%)	26/304 (8.55%)	23/304 (7.57%)	19/303 (6.27%)
VITREOUS FLOATERS [A] [2]*	33/304 (10.86%)	40/304 (13.16%)	23/304 (7.57%)	21/303 (6.93%)
Infections and infestations				
BRONCHITIS [A]*	16/304 (5.26%)	12/304 (3.95%)	10/304 (3.29%)	16/303 (5.28%)
NASOPHARYNGITIS [A]*	23/304 (7.57%)	33/304 (10.86%)	24/304 (7.89%)	26/303 (8.58%)
UPPER RESPIRATORY TRACT INFECTION [A]*	13/304 (4.28%)	11/304 (3.62%)	14/304 (4.61%)	18/303 (5.94%)
URINARY TRACT INFECTION [A]*	16/304 (5.26%)	12/304 (3.95%)	15/304 (4.93%)	13/303 (4.29%)
Investigations				
INTRAOCULAR PRESSURE INCREASED [A] [2]*	21/304 (6.91%)	14/304 (4.61%)	12/304 (3.95%)	15/303 (4.95%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection 2.0mg Q4	Aflibercept Injection 0.5mg Q4	Aflibercept Injection 2.0mg Q8
Nervous system disorders				
HEADACHE [A*]	19/304 (6.25%)	11/304 (3.62%)	11/304 (3.62%)	12/303 (3.96%)
Vascular disorders				
HYPERTENSION [A*]	23/304 (7.57%)	21/304 (6.91%)	20/304 (6.58%)	20/303 (6.6%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA 13.0

[1] Fellow Eye

[2] Study Eye

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals
Phone:
Email: clinicaltrials@regeneron.com

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	◉	◉	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00527423

Submitted Date: November 1, 2011 (v8)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification:	November 2011
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	October 2011 [Actual]
Study Completion:	October 2011 [Actual]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Certification/Extension First Submitted:	April 25, 2011
Certification/Extension First Submitted that Met QC Criteria:	April 25, 2011
Certification/Extension First Posted:	April 29, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	November 1, 2011
Last Update Posted:	November 6, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor

Collaborators: Bayer

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

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United States, Utah

Salt Lake City, Utah, United States, 84107

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History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
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Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: June 20, 2011 (v7)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: June 2011

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: October 2011 [Anticipated]

Study Completion: October 2011 [Anticipated]

First Submitted: September 6, 2007

First Submitted that Met QC Criteria: September 7, 2007

First Posted: September 10, 2007 [Estimate]

Certification/Extension First Submitted: April 25, 2011

Certification/Extension First Submitted that Met QC Criteria: April 25, 2011

Certification/Extension First Posted: April 29, 2011 [Estimate]

Last Update Submitted that Met QC Criteria: June 20, 2011

Last Update Posted: June 28, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Kristine Erickson
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

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ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
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2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	◉	◉	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: April 25, 2011 (v6)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2011

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: October 2011 [Anticipated]

Study Completion: October 2011 [Anticipated]

First Submitted: September 6, 2007

First Submitted that Met QC Criteria: September 7, 2007

First Posted: September 10, 2007 [Estimate]

Certification/Extension First Submitted: April 25, 2011

Certification/Extension First Submitted that Met QC Criteria: April 25, 2011

Certification/Extension First Posted: April 29, 2011 [Estimate]

Last Update Submitted that Met QC Criteria: April 25, 2011

Last Update Posted: April 29, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

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History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

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Study Record Versions

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2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

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3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
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9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: February 11, 2011 (v5)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

	Eye in Subjects With Neovascular Age-related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	February 2011
Overall Status:	Active, not recruiting
Study Start:	August 2007
Primary Completion:	October 2011 [Anticipated]
Study Completion:	October 2011 [Anticipated]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Last Update Submitted that Met QC Criteria:	February 11, 2011
Last Update Posted:	February 14, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
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Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

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ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

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7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: December 3, 2009 (v4)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: December 2009

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: August 2010 [Anticipated]

Study Completion: September 2010 [Anticipated]

First Submitted: September 6, 2007

First Submitted that Met QC Criteria: September 7, 2007

First Posted: September 10, 2007 [Estimate]

Last Update Submitted that Met QC Criteria: December 3, 2009

Last Update Posted: December 4, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

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Salt Lake City, Utah, United States, 84107

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ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	◉	◉	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: April 9, 2009 (v3)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification: April 2009

Overall Status: Active, not recruiting

Study Start: August 2007

Primary Completion: August 2010 [Anticipated]

Study Completion: September 2010 [Anticipated]

First Submitted: September 6, 2007

First Submitted that Met QC Criteria: September 7, 2007

First Posted: September 10, 2007 [Estimate]

Last Update Submitted that Met QC Criteria: April 9, 2009

Last Update Posted: April 10, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Robert Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

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ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	◉	◉	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: July 3, 2008 (v2)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

Official Title:	An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Subjects With Neovascular Age-related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	July 2008
Overall Status:	Active, not recruiting
Study Start:	August 2007
Primary Completion:	August 2010 [Anticipated]
Study Completion:	September 2010 [Anticipated]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Last Update Submitted that Met QC Criteria:	July 3, 2008
Last Update Posted:	July 8, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 165 [Anticipated]

Arms and Interventions

Intervention Details:

Biological: VEGF Trap Eye
Intravitreal injection

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Westlake Village, California, United States, 91361

United States, Florida

Fort Meyers, Florida, United States, 33907

Ft. Lauderdale, Florida, United States, 33334

Ft. Myers, Florida, United States, 33912

Stuart, Florida, United States, 34994

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ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Open-Label, Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
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6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: September 7, 2007 (v1)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Open-Label, Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Neovascular Age-Related Macular Degeneration

Official Title:	An Open-Label, Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-Eye in Subjects With Neovascular Age-Related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	September 2007
Overall Status:	Not yet recruiting
Study Start:	August 2007
Primary Completion:	
Study Completion:	September 2010 [Anticipated]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Last Update Submitted that Met QC Criteria:	September 7, 2007
Last Update Posted:	September 10, 2007 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Open Label Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment. Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: N/A

Enrollment: 215 [Anticipated]

Arms and Interventions

Intervention Details:

Biological: VEGF Trap Eye
Intravitreal injection

Outcome Measures

Primary Outcome Measures:

1. Safety - Assessment of adverse events and intraocular pressure. Efficacy - Frequency of retreatment between baseline and end of study.
   3 years

Secondary Outcome Measures:

2. Change in letters read from both baseline of this study and baseline of the previous study the subject participated in.
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in:

VGFT-OD-0502 Open-label extension and completed Termination Visit VGFT-OD-0508 Completed through Visit 16 (Week 52) VGFT-OD-0603 Completed through Visit 26 (Week 52)

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Central Contact: Avner Ingerman, MD
Telephone: 914-345-7520
Email: avner.ingerman@regeneron.com

Central Contact Backup: Karen Chu, MS

Telephone: 914-345-7918

Email: karen.chu@regeneron.com

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

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History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	◉	◉	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00527423

Submitted Date: June 10, 2013 (v11)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: A Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

	Eye in Subjects With Neovascular Age-related Macular Degeneration
Secondary IDs:	

Study Status

Record Verification:	June 2013
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	October 2011 [Actual]
Study Completion:	October 2011 [Actual]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Results First Submitted:	November 2, 2012
Results First Submitted that Met QC Criteria:	June 10, 2013
Results First Posted:	June 12, 2013 [Estimate]
Certification/Extension First Submitted:	April 25, 2011
Certification/Extension First Submitted that Met QC Criteria:	April 25, 2011
Certification/Extension First Posted:	April 29, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	June 10, 2013

Last Update Posted: June 12, 2013 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party: Sponsor

Collaborators: Bayer

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms: 1

Masking: Single (Participant)

Allocation: N/A

Enrollment: 157 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye)	Drug: VEGF Trap Eye Intravitreal injection Other Names: • IVT

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation

- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Westlake Village, California, United States, 91361

United States, Florida

Ft. Myers, Florida, United States, 33912

Stuart, Florida, United States, 34994

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Glenview, Illinois, United States, 60026

United States, Indiana

Indianapolis, Indiana, United States, 47280

United States, Maryland

Baltimore, Maryland, United States, 21287

Hagerstown, Maryland, United States, 21740

United States, Massachusetts

Boston, Massachusetts, United States, 02114

West Springfield, Massachusetts, United States, 01089

United States, New Jersey

Toms River, New Jersey, United States, 08755

United States, New York

Lynbrook, New York, United States, 11563

United States, North Carolina

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

United States, South Carolina

W. Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Austin, Texas, United States, 78705

Fort Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	This study was conducted at 35 sites in the United States that participated in the Phase 1 and Phase 2 studies VGFT OD-0502 (NCT00320775), -0508 (NCT00320788), or -0603 (NCT00383370). The recruitment period occurred between 19 Oct 2007 and 29 Oct 2008.
Pre-assignment Details	One hundred fifty seven participants were eligible if they had neovascular Age-related Macular Degeneration (AMD) and completed dosing in the Phase 1 and Phase 2 studies VGFT-OD-0502 (NCT00320775), -0508 (NCT00320788), or -0603 (NCT00383370). For each subject, only one eye was designated as the study eye.

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152, and a 4-week follow-up visit at week 156. Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or "as needed" dosing). If, at any point during the study, in the investigator's opinion, a participant required dosing or evaluation more frequently than every 8 weeks, monthly visits and dosing were permitted. The maximum frequency of injection into the study eye was every 4 weeks.

Overall Study

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Started	157
Completed	120
Not Completed	37
Protocol Violation	1
Adverse Event	5
Physician Decision	4
Withdrawal by Subject	10
Lost to Follow-up	4
OTHER	4
Death	9

Baseline Characteristics

Reporting Groups

	Description

Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152, and a 4-week follow-up visit at week 156. Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or "as needed" dosing). If, at any point during the study, in the investigator's opinion, a participant required dosing or evaluation more frequently than every 8 weeks, monthly visits and dosing were permitted. The maximum frequency of injection into the study eye was every 4 weeks.

Baseline Measures

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Overall Number of Participants		157
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	157 Participants
		77.9 (8.16)
Sex: Female, Male Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	157 Participants
	Female	96 61.15%
	Male	61 38.85%
Ethnicity (NIH/OMB) Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	157 Participants
	Hispanic or Latino	4 2.55%
	Not Hispanic or Latino	153 97.45%
	Unknown or Not Reported	0 0%
Race (NIH/OMB) Measure type: Count of Participants	Number Analyzed	157 Participants

Unit of measure: Participants		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
	American Indian or Alaska Native	1 0.64%
	Asian	0 0%
	Native Hawaiian or Other Pacific Islander	0 0%
	Black or African American	0 0%
	White	156 99.36%
	More than one race	0 0%
	Unknown or Not Reported	0 0%
Baseline Best Corrected Visual Acuity (BCVA) [1] Mean (Standard Deviation) Unit of measure: scores on a scale	Number Analyzed	157 Participants
		61.3 (15.35)
		[1] Measure Description: For BCVA, tested via the 4 meter ETDRS (Early Treatment Diabetic Retinopathy Study) protocol, 83 letter or more would represent 20/20 vision or better which would be considered an excellent outcome. Although, the ETDRS charts include 100 letters as the maximum possible score. The worst outcome is 0 letters read.

		Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Baseline Intraocular Pressure [1] Mean (Standard Deviation) Unit of measure: mmHg	Number Analyzed	157 Participants
		14.5 (3.12)
		[1] Measure Description: Intraocular pressure was measured in the study and fellow eyes using applanation tonometry or Tonopen at every study visit pre-dose, and 30 to 60 minutes post-injection.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Participants With Adverse Events (AE)
Measure Description	Number of participants with AEs summarized by category
Time Frame	Baseline of this study to Wk 152

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152, and a 4-week follow-up visit at week 156. Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or "as needed" dosing). If, at any point during the study, in the investigator's opinion, a participant required dosing or evaluation more frequently than every 8 weeks, monthly visits and dosing were permitted. The maximum frequency of injection into the study eye was every 4 weeks.

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Overall Number of Participants Analyzed	157
Number of Participants With Adverse Events (AE) Measure Type: Number Unit of Measure: participants	
Number of participants with any AE	154
Any ocular AE (Study eye and Fellow eye)	138
Any non ocular AE	151
Any treatment related AE (Ocular and non ocular)	5
Any SAE	72
Any AEs leading to withdrawal from study	5
Any Death due to AE	11

2. Secondary Outcome Measure:

Measure Title	Frequency (Number of Injections)
Measure Description	Frequency (number of injections) of PRN treatment from baseline of this study to week 152 (end of treatment).
Time Frame	Baseline of this study to Wk 152

Analysis Population Description

A total of 1116 PRN injections were administered into the study eyes of 135 participants between baseline of this study to Week 152 (end of treatment). Of the 157 enrolled participants, 22 received no injections, and 15 received 1 injection.

Reporting Groups

	Description

Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152 (end of treatment), and a 4-week follow-up visit at week 156 (end of study). Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Overall Number of Participants Analyzed	157
Frequency (Number of Injections) Measure Type: Median (Full Range) Unit of Measure: Injections	6.0 (0 to 26)

3. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline of Original Study in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score of Study Eye - Observed Values
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity of: letter score of 73 to 25 (20/40 to 20/320) in the study eye; a higher score represents better functioning.
Time Frame	Baseline of original study to Wk 156

Analysis Population Description

[Not Specified]

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152, and a 4-week follow-up visit at week 156. Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or

Measured Values

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Overall Number of Participants Analyzed	157
Mean Change From Baseline of Original Study in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score of Study Eye - Observed Values Measure Type: Mean (Standard Deviation) Unit of Measure: letters read	4.1 (17.71)

Reported Adverse Events

Time Frame	Baseline of this study to Wk 156
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg	The study consisted of a treatment period from day 1 to week 152, and a 4-week follow-up visit at week 156. Participants were scheduled to return to the clinical site every 8 weeks. At each visit, the investigator determined the need for an Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) based on his/her assessment of the participant (PRN or "as needed" dosing). If, at any point during the study, in the investigator's opinion, a participant required dosing or evaluation more frequently than every 8 weeks, monthly visits and dosing were permitted. The maximum frequency of injection into the study eye was every 4 weeks.

All-Cause Mortality

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
	Affected/At Risk (%)
Total	/

Serious Adverse Events

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
	Affected/At Risk (%)
Total	72/157 (45.86%)
Blood and lymphatic system disorders	
Anaemia [A*]	1/157 (0.64%)
Cardiac disorders	
Acute myocardial infarction [A*]	2/157 (1.27%)
Angina pectoris [A*]	1/157 (0.64%)
Arteriosclerosis coronary artery [A*]	2/157 (1.27%)
Atrial fibrillation [A*]	7/157 (4.46%)
Atrioventricular block [A*]	1/157 (0.64%)
Bradycardia [A*]	2/157 (1.27%)
Cardiac arrest [A*]	1/157 (0.64%)
Cardiac failure congestive [A*]	1/157 (0.64%)
Coronary artery disease [A*]	1/157 (0.64%)
Coronary artery stenosis [A*]	2/157 (1.27%)
Myocardial infarction [A*]	2/157 (1.27%)
Pericarditis [A*]	1/157 (0.64%)
Endocrine disorders	

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Goitre [A*]	1/157 (0.64%)
Eye disorders	
Cataract [A [1]*]	1/157 (0.64%)
Lens dislocation [A [2]*]	1/157 (0.64%)
Retinal haemorrhage [A [1]*]	2/157 (1.27%)
Retinal oedema [A [1]*]	1/157 (0.64%)
Visual acuity reduced [A [1]*]	4/157 (2.55%)
Gastrointestinal disorders	
Diarrhoea [A*]	1/157 (0.64%)
Duodenal ulcer perforation [A*]	1/157 (0.64%)
Eructation [A*]	1/157 (0.64%)
Gastric ulcer [A*]	2/157 (1.27%)
Inguinal hernia [A*]	1/157 (0.64%)
Intestinal obstruction [A*]	1/157 (0.64%)
General disorders	
Chest pain [A*]	1/157 (0.64%)
Gait disturbance [A*]	1/157 (0.64%)
Metaplasia [A*]	1/157 (0.64%)
Hepatobiliary disorders	
Bile duct stone [A*]	1/157 (0.64%)
Cholecystitis [A*]	1/157 (0.64%)
Cholecystitis acute [A*]	1/157 (0.64%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Cholelithiasis [A*]	3/157 (1.91%)
Immune system disorders	
Sarcoidosis [A*]	1/157 (0.64%)
Infections and infestations	
Bronchitis [A*]	2/157 (1.27%)
Cellulitis [A*]	1/157 (0.64%)
Clostridium difficile colitis [A*]	1/157 (0.64%)
Enteritis infectious [A*]	1/157 (0.64%)
Gastroenteritis [A*]	1/157 (0.64%)
Pneumonia [A*]	5/157 (3.18%)
Sepsis [A*]	1/157 (0.64%)
Urinary tract infection [A*]	1/157 (0.64%)
Viral infection [A*]	1/157 (0.64%)
Injury, poisoning and procedural complications	
Accident [A*]	1/157 (0.64%)
Cervical vertebral fracture [A*]	1/157 (0.64%)
Concussion [A*]	1/157 (0.64%)
Corneal abrasion [A [1]*]	1/157 (0.64%)
Facial bones fracture [A*]	1/157 (0.64%)
Fall [A*]	7/157 (4.46%)
Femoral neck fracture [A*]	2/157 (1.27%)
Head injury [A*]	1/157 (0.64%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Incisional hernia [A*]	1/157 (0.64%)
Periorbital haematoma [A*]	1/157 (0.64%)
Pubis fracture [A*]	1/157 (0.64%)
Spinal compression fracture [A*]	1/157 (0.64%)
Investigations	
Intraocular pressure increased [A [2]*]	1/157 (0.64%)
Metabolism and nutrition disorders	
Dehydration [A*]	4/157 (2.55%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A*]	1/157 (0.64%)
Intervertebral disc protrusion [A*]	1/157 (0.64%)
Lumbar spinal stenosis [A*]	1/157 (0.64%)
Osteoarthritis [A*]	4/157 (2.55%)
Rotator cuff syndrome [A*]	1/157 (0.64%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Adenoma benign [A*]	1/157 (0.64%)
Bladder neoplasm [A*]	1/157 (0.64%)
Bladder transitional cell carcinoma [A*]	1/157 (0.64%)
Breast cancer [A*]	1/157 (0.64%)
Breast cancer metastatic [A*]	1/157 (0.64%)
Breast cancer recurrent [A*]	1/157 (0.64%)
Chronic lymphocytic leukaemia [A*]	1/157 (0.64%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Colon cancer [A*]	2/157 (1.27%)
Head and neck cancer [A*]	2/157 (1.27%)
Lung neoplasm malignant [A*]	1/157 (0.64%)
Lung squamous cell carcinoma stage unspecified [A*]	2/157 (1.27%)
Metastases to liver [A*]	1/157 (0.64%)
Metastatic renal cell carcinoma [A*]	1/157 (0.64%)
Non-small cell lung cancer metastatic [A*]	1/157 (0.64%)
Prostate cancer [A*]	2/157 (1.27%)
Renal cell carcinoma [A*]	1/157 (0.64%)
Renal cell carcinoma recurrent [A*]	1/157 (0.64%)
Small cell lung cancer stage unspecified [A*]	1/157 (0.64%)
Squamous cell carcinoma [A*]	2/157 (1.27%)
Squamous cell carcinoma of skin [A*]	5/157 (3.18%)
Tongue neoplasm malignant stage unspecified [A*]	1/157 (0.64%)
Tonsil cancer [A*]	1/157 (0.64%)
Transitional cell carcinoma [A*]	1/157 (0.64%)
Nervous system disorders	
Basal ganglia haemorrhage [A*]	1/157 (0.64%)
Carotid artery stenosis [A*]	2/157 (1.27%)
Cerebrovascular accident [A*]	2/157 (1.27%)
Dementia [A*]	2/157 (1.27%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Dizziness [A*]	1/157 (0.64%)
Headache [A*]	1/157 (0.64%)
Hypoaesthesia [A*]	1/157 (0.64%)
Lacunar infarction [A*]	1/157 (0.64%)
Presyncope [A*]	1/157 (0.64%)
Syncope [A*]	1/157 (0.64%)
Transient ischaemic attack [A*]	1/157 (0.64%)
Psychiatric disorders	
Hallucination [A*]	1/157 (0.64%)
Mental disorder [A*]	1/157 (0.64%)
Mental status changes [A*]	1/157 (0.64%)
Renal and urinary disorders	
Haematuria [A*]	1/157 (0.64%)
Renal failure [A*]	1/157 (0.64%)
Respiratory, thoracic and mediastinal disorders	
Chronic obstructive pulmonary disease [A*]	1/157 (0.64%)
Dyspnoea [A*]	2/157 (1.27%)
Hypoxia [A*]	1/157 (0.64%)
Pleural effusion [A*]	1/157 (0.64%)
Pulmonary embolism [A*]	2/157 (1.27%)
Pulmonary oedema [A*]	1/157 (0.64%)
Respiratory failure [A*]	1/157 (0.64%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Vascular disorders	
Hypertension [A*]	1/157 (0.64%)
Hypotension [A*]	1/157 (0.64%)
Orthostatic hypotension [A*]	1/157 (0.64%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 14.1

[1] Ocular AE Study Eye

[2] Ocular AE Fellow Eye

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
	Affected/At Risk (%)
Total	149/157 (94.9%)
Blood and lymphatic system disorders	
Anaemia [A*]	8/157 (5.1%)
Eye disorders	
Age-related macular degeneration [A [1]*]	18/157 (11.46%)
Blepharitis [A [1]*]	13/157 (8.28%)
Cataract [A [1]*]	21/157 (13.38%)
Cataract nuclear [A [1]*]	9/157 (5.73%)
Conjunctival haemorrhage [A [1]*]	12/157 (7.64%)
Detachment of retinal pigment epithelium [A [1]*]	8/157 (5.1%)
Dry eye [A [1]*]	10/157 (6.37%)

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Eye pain [A] [1]*	8/157 (5.1%)
Eye pruritus [A] [2]*	8/157 (5.1%)
Posterior capsule opacification [A] [2]*	10/157 (6.37%)
Retinal haemorrhage [A] [1]*	19/157 (12.1%)
Visual acuity reduced [A] [1]*	13/157 (8.28%)
Vitreous detachment [A] [1]*	11/157 (7.01%)
Vitreous floaters [A] [1]*	8/157 (5.1%)
Gastrointestinal disorders	
Constipation [A]*	12/157 (7.64%)
Diarrhoea [A]*	16/157 (10.19%)
Gastrooesophageal reflux disease [A]*	9/157 (5.73%)
Nausea [A]*	14/157 (8.92%)
Immune system disorders	
Seasonal allergy [A]*	15/157 (9.55%)
Infections and infestations	
Bronchitis [A]*	17/157 (10.83%)
Influenza [A]*	10/157 (6.37%)
Nasopharyngitis [A]*	26/157 (16.56%)
Sinusitis [A]*	16/157 (10.19%)
Upper respiratory tract infection [A]*	24/157 (15.29%)
Urinary tract infection [A]*	25/157 (15.92%)
Injury, poisoning and procedural complications	

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Contusion [A*]	10/157 (6.37%)
Fall [A*]	29/157 (18.47%)
Investigations	
Blood glucose increased [A*]	13/157 (8.28%)
Blood pressure increased [A*]	9/157 (5.73%)
Protein urine present [A*]	13/157 (8.28%)
White blood cell count increased [A*]	12/157 (7.64%)
White blood cells urine positive [A*]	9/157 (5.73%)
Metabolism and nutrition disorders	
Hypercholesterolaemia [A*]	9/157 (5.73%)
Musculoskeletal and connective tissue disorders	
Arthralgia [A*]	15/157 (9.55%)
Arthritis [A*]	12/157 (7.64%)
Back pain [A*]	12/157 (7.64%)
Osteoarthritis [A*]	9/157 (5.73%)
Pain in extremity [A*]	9/157 (5.73%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Basal cell carcinoma [A*]	9/157 (5.73%)
Nervous system disorders	
Dizziness [A*]	10/157 (6.37%)
Headache [A*]	8/157 (5.1%)
Psychiatric disorders	

	Intravitreal Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg
Depression [A*]	14/157 (8.92%)
Insomnia [A*]	13/157 (8.28%)
Respiratory, thoracic and mediastinal disorders	
Cough [A*]	14/157 (8.92%)
Dyspnoea [A*]	9/157 (5.73%)
Vascular disorders	
Hypertension [A*]	26/157 (16.56%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA Version 14.1

[1] Ocular AE Fellow Eye

[2] Ocular AE Study Eye

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator
Organization: Regeneron Pharmaceuticals
Phone:
Email: clinicaltrials@regeneron.com

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	○	○	May 9, 2012	Study Status
10	◉	◉	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00527423

Submitted Date: September 27, 2012 (v10)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: A Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification:	September 2012
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	October 2011 [Actual]
Study Completion:	October 2011 [Actual]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Certification/Extension First Submitted:	April 25, 2011
Certification/Extension First Submitted that Met QC Criteria:	April 25, 2011
Certification/Extension First Posted:	April 29, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	September 27, 2012
Last Update Posted:	October 4, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor

Collaborators: Bayer

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Dosing Regimen 1	Drug: VEGF Trap Eye Intravitreal injection Other Names: • IVT
Experimental: Dosing Regimen 2	Drug: VEGF Trap Eye Intravitreal injection Other Names: • IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Westlake Village, California, United States, 91361

United States, Florida

Ft. Myers, Florida, United States, 33912

Stuart, Florida, United States, 34994

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Glenview, Illinois, United States, 60026

United States, Indiana

Indianapolis, Indiana, United States, 47280

United States, Maryland

Baltimore, Maryland, United States, 21287

Hagerstown, Maryland, United States, 21740

United States, Massachusetts

Boston, Massachusetts, United States, 02114

West Springfield, Massachusetts, United States, 01089

United States, New Jersey

Toms River, New Jersey, United States, 08755

United States, New York

Lynbrook, New York, United States, 11563

United States, North Carolina

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

United States, South Carolina

W. Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Austin, Texas, United States, 78705

Fort Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

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Citations:

Links:

Available IPD/Information:

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00527423

Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Latest version (submitted June 10, 2013) on ClinicalTrials.gov

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- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	September 7, 2007	None (earliest Version on record)
2	○	○	July 3, 2008	Recruitment Status, Study Status, Study Design, Outcome Measures, Study Identification, Contacts/Locations, Eligibility and Study Description

Version	A	B	Submitted Date	Changes
3	○	○	April 9, 2009	Contacts/Locations, Arms and Interventions, Study Status, Oversight, Sponsor/Collaborators and Study Identification
4	○	○	December 3, 2009	Sponsor/Collaborators and Study Status
5	○	○	February 11, 2011	Study Status and Study Design
6	○	○	April 25, 2011	Study Status
7	○	○	June 20, 2011	Study Status, Contacts/Locations and Sponsor/Collaborators
8	○	○	November 1, 2011	Recruitment Status, Study Status, Sponsor/Collaborators and Contacts/Locations
9	◉	◉	May 9, 2012	Study Status
10	○	○	September 27, 2012	Arms and Interventions, Study Status and Study Identification
11	○	○	June 10, 2013	Outcome Measures, Study Status, More Information, Arms and Interventions, Reported Adverse Events, Baseline Characteristics, Participant Flow and Study Design

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00527423

Submitted Date: May 9, 2012 (v9)

Study Identification

Unique Protocol ID: VGFT-OD-0702

Brief Title: Randomized, Single-Masked, Long-Term, Safety and Tolerability Study of VEGF Trap-Eye in AMD

Official Title: An Randomized, Single-Masked , Long-Term, Safety and Tolerability Study of Intravitreal VEGF Trap-

Eye in Subjects With Neovascular Age-related Macular Degeneration

Secondary IDs:

Study Status

Record Verification:	November 2011
Overall Status:	Completed
Study Start:	August 2007
Primary Completion:	October 2011 [Actual]
Study Completion:	October 2011 [Actual]
First Submitted:	September 6, 2007
First Submitted that Met QC Criteria:	September 7, 2007
First Posted:	September 10, 2007 [Estimate]
Certification/Extension First Submitted:	April 25, 2011
Certification/Extension First Submitted that Met QC Criteria:	April 25, 2011
Certification/Extension First Posted:	April 29, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	May 9, 2012
Last Update Posted:	May 14, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	Sponsor

Collaborators: Bayer

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: No

Study Description

Brief Summary: Rollover study for subjects in prior VEGF Trap-Eye Phase I and II studies. Primary objective is to assess long-term safety and tolerability of continuing intravitreal treatment in subjects with wet age-related macular degeneration.

Detailed Description: Randomized, Single-Masked Phase II study for subjects previously enrolled in Phase I and II studies for wet age-related macular degeneration with VEGF Trap-Eye intravitreal injection as treatment.Long term (3 years) treatment is intended to measure safety and tolerability, as well as frequency of re-treatment and the effect of VEGF Trap-Eye on best corrected visual acuity (BCVA).

Conditions

Conditions: Macular Degeneration

Keywords: VEGF Trap-Eye
Macular Degeneration
AMD
Neovascular Age-Related Macular Degeneration

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 157 [Actual]

Arms and Interventions

Intervention Details:

Drug: VEGF Trap Eye
Intravitreal injection

Other Names:

- IVT

Outcome Measures

Primary Outcome Measures:

1. Assessment of safety and tolerability as assessed by adverse events, laboratory assessments, vital signs, visual acuity and intraocular pressure.
   3 years

Secondary Outcome Measures:

2. The secondary endpoints include: Frequency of re-treatment • Visual acuity parameters (ETDRS letters)
   3 years

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Prior participation in VEGF Trap-Eye Phase I and II studies

Exclusion Criteria:

- Any ocular or systemic adverse events that would preclude participation
- Presence of any condition that would jeopardize subject's participation

Contacts/Locations

Study Officials: Clinical Trial Management
Study Director
Regeneron Pharmaceuticals

Locations: **United States, Arizona**

Peoria, Arizona, United States, 85381

Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

Beverly Hills, California, United States, 90211

Loma Linda, California, United States, 92354

Palm Springs, California, United States, 92262

Pasadena, California, United States, 91105

Poway, California, United States, 92064

Westlake Village, California, United States, 91361

United States, Florida

Ft. Myers, Florida, United States, 33912

Stuart, Florida, United States, 34994

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Illinois

Glenview, Illinois, United States, 60026

United States, Indiana

Indianapolis, Indiana, United States, 47280

United States, Maryland

Baltimore, Maryland, United States, 21287

Hagerstown, Maryland, United States, 21740

United States, Massachusetts

Boston, Massachusetts, United States, 02114

West Springfield, Massachusetts, United States, 01089

United States, New Jersey

Toms River, New Jersey, United States, 08755

United States, New York

Lynbrook, New York, United States, 11563

United States, North Carolina

Charlotte, North Carolina, United States, 28210

United States, Oklahoma

Oklahoma City, Oklahoma, United States, 73104

United States, Oregon

Portland, Oregon, United States, 97210

United States, South Carolina

W. Columbia, South Carolina, United States, 29169

United States, South Dakota

Rapid City, South Dakota, United States, 57701

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Austin, Texas, United States, 78705

Fort Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 1828

Samsung Bioepis Exhibit 1017, pg. 1828

Version	A	B	Submitted Date	Changes
1	O	O	March 17, 2008	None (earliest Version on record)
2	O	O	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	O	O	June 19, 2008	Contacts/Locations and Study Status
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	◉	◉	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

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Study NCT00637377

Submitted Date: December 16, 2011 (v26)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: December 2011

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	December 16, 2011
Last Update Posted:	January 23, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

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Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

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Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

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Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

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Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

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Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

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Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

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Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

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Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

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Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

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Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1

Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants	291	309	296	306	1202

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation)	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/291 (12.37%)	50/309 (16.18%)	42/297 (14.14%)	50/307 (16.29%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	1/307 (0.33%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac failure [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	3/307 (0.98%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Eye disorders				
Cataract (Fellow Eye) [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cataract (Study Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cataract cortical (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation (Fellow Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hyphaema (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Macular cyst (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Fellow Eye) [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Macular hole (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Maculopathy (Fellow Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification (Study Eye) [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal detachment (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Retinal haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal haemorrhage (Study Eye) [A*]	1/291 (0.34%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epithelial tear (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epitheliopathy (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal pigment epitheliopathy (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced (Fellow Eye) [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)
Visual acuity reduced (Study Eye) [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	5/307 (1.63%)
Vitreous haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Colitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
General disorders				
Chest pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Hepatobiliary disorders				
Cholecystitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pneumonia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	2/307 (0.65%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urinary tract infection [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Fall [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Lumbar vertebral fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Upper limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Metabolism and nutrition disorders				
Dehydration [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Syncope [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Renal failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Rash [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cataract operation [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	208/291 (71.48%)	209/309 (67.64%)	209/297 (70.37%)	217/307 (70.68%)
Cardiac disorders				
Atrioventricular block first degree [A*]	12/291 (4.12%)	22/309 (7.12%)	18/297 (6.06%)	17/307 (5.54%)
Eye disorders				
Cataract (Study Eye) [A*]	14/291 (4.81%)	17/309 (5.5%)	12/297 (4.04%)	13/307 (4.23%)
Choroidal neovascularisation (Fellow Eye) [A*]	14/291 (4.81%)	14/309 (4.53%)	15/297 (5.05%)	17/307 (5.54%)
Conjunctival haemorrhage (Study Eye) [A*]	23/291 (7.9%)	24/309 (7.77%)	37/297 (12.46%)	30/307 (9.77%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Detachment of retinal pigment epithelium (Study Eye) [A*]	26/291 (8.93%)	26/309 (8.41%)	24/297 (8.08%)	25/307 (8.14%)
Eye pain (Study Eye) [A*]	27/291 (9.28%)	33/309 (10.68%)	22/297 (7.41%)	21/307 (6.84%)
Macular cyst (Study Eye) [A*]	15/291 (5.15%)	6/309 (1.94%)	7/297 (2.36%)	6/307 (1.95%)
Macular degeneration (Fellow Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	25/297 (8.42%)	33/307 (10.75%)
Macular degeneration (Study Eye) [A*]	27/291 (9.28%)	28/309 (9.06%)	27/297 (9.09%)	33/307 (10.75%)
Ocular hyperaemia (Study Eye) [A*]	18/291 (6.19%)	13/309 (4.21%)	13/297 (4.38%)	9/307 (2.93%)
Retinal cyst (Study Eye) [A*]	10/291 (3.44%)	16/309 (5.18%)	14/297 (4.71%)	11/307 (3.58%)
Retinal degeneration (Study Eye) [A*]	23/291 (7.9%)	27/309 (8.74%)	20/297 (6.73%)	18/307 (5.86%)
Retinal haemorrhage (Fellow Eye) [A*]	21/291 (7.22%)	17/309 (5.5%)	12/297 (4.04%)	21/307 (6.84%)
Retinal haemorrhage (Study Eye) [A*]	39/291 (13.4%)	41/309 (13.27%)	39/297 (13.13%)	37/307 (12.05%)
Retinal oedema (Study Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	14/297 (4.71%)	23/307 (7.49%)
Retinal pigment epitheliopathy (Study Eye) [A*]	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	24/307 (7.82%)
Visual acuity reduced (Fellow Eye) [A*]	10/291 (3.44%)	10/309 (3.24%)	13/297 (4.38%)	19/307 (6.19%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Visual acuity reduced (Study Eye) A*	19/291 (6.53%)	25/309 (8.09%)	33/297 (11.11%)	30/307 (9.77%)
Vitreous detachment (Study Eye) A*	10/291 (3.44%)	19/309 (6.15%)	10/297 (3.37%)	15/307 (4.89%)
General disorders				
Pyrexia A*	9/291 (3.09%)	7/309 (2.27%)	15/297 (5.05%)	5/307 (1.63%)
Infections and infestations				
Influenza A*	8/291 (2.75%)	14/309 (4.53%)	8/297 (2.69%)	17/307 (5.54%)
Nasopharyngitis A*	28/291 (9.62%)	15/309 (4.85%)	26/297 (8.75%)	19/307 (6.19%)
Investigations				
Intraocular pressure increased A*	23/291 (7.9%)	30/309 (9.71%)	21/297 (7.07%)	22/307 (7.17%)
Nervous system disorders				
Headache A*	12/291 (4.12%)	9/309 (2.91%)	12/297 (4.04%)	17/307 (5.54%)
Vascular disorders				
Hypertension A*	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	19/307 (6.19%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	O	O	June 19, 2008	Contacts/Locations and Study Status
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
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22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	◉	◉	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 6, 2011 (v25)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EudraCT: 2007-000583-25

Study Status

Record Verification: June 2011

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: June 6, 2011

Last Update Posted: June 7, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Biological: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Biological: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Biological: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in Best Corrected Visual Acuity (BCVA) as measured by ETDRS (Early Treatment Diabetic Retinopathy Study) letter score at Week 52

Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 (National Eye Institute Visual Functioning Questionaire) score at Week 52
   Week 52
5. Mean change from baseline in CNV (Choroidal Neovascularization) area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.
- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

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Barcelona, Spain, 08036

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Madrid, Spain, 28046

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Sevilla, Spain, 41013

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Valencia, Spain, 46015

Valladolid, Spain, 47005

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

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12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
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Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
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29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: May 23, 2011 (v24)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EudraCT: 2007-000583-25

Study Status

Record Verification: May 2011

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: May 23, 2011

Last Update Posted: May 24, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	◉	◉	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 21, 2011 (v23)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: February 2011

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: February 21, 2011

Last Update Posted: February 23, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
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Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

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United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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Study Record Versions

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2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
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4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
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14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
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17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
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22	◉	◉	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 30, 2010 (v22)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 30, 2010

Last Update Posted: December 1, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

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Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

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Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

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São Paulo, Sao Paulo, Brazil, 05651-901

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Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

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Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

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Nantes, Cedex 1, France, 44093

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Besancon, France, 25030

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Dijon, France, 21079

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Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

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Darmstadt, Hessen, Germany, 64297

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Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

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Mainz, Rheinland-Pfalz, Germany, 55131

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Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

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Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

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Mumbai, India, 400 050

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New Delhi, India, 110029

Orissa, India, 751 024

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Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

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Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

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Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

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Nagoya, Aichi, Japan, 467-8602

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Japan, Gunma

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Seongnam, Gyeonggido, Korea, Republic of, 463 707

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Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

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Riga, Latvia, 1002

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Riga, Latvia, 1050

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Monterrey, Nuevo Leon, Mexico, 64480

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Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

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Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

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Porto, Portugal, 4200-319

Singapore

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Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

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Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

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Santiago de Compostela, A Coruña, Spain, 15705

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Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

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Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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Study Record Versions

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2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

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11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	◉	◉	October 6, 2010	Study Status
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24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
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27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: October 6, 2010 (v21)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	October 2010
Overall Status:	Active, not recruiting
Study Start:	April 2008
Primary Completion:	September 2010 [Anticipated]
Study Completion:	August 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	October 6, 2010
Last Update Posted:	October 7, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	◉	◉	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: July 9, 2010 (v20)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: July 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Anticipated]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: July 9, 2010

Last Update Posted: July 12, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
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- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

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Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

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Netherlands

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Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

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Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

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Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

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Banska Bystrica, Slovakia, 97517

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Barcelona, Spain, 08022

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Barcelona, Spain, 08036

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Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

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Valencia, Spain, 46014

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Valladolid, Spain, 47005

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Linköping, Sweden, 58185

Stockholm, Sweden, 11282

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London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

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25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 19, 2010 (v19)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: February 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: October 2010 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: February 19, 2010

Last Update Posted: February 22, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Tirol

Innsbruck, Tirol, Austria, 6020

Austria

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

São Paulo, SP, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

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Paris, Cedex 12, France, 75557

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris Cedex 10, France, 75475

Paris, France, 75015

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Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64276

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45147

Köln, Nordrhein-Westfalen, Germany, 50931

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

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Budapest, Hungary, 1036

Budapest, Hungary, 1089

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

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Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

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Gugarat, India

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Kolkata, India, 700073

Mumbai, India, 400 050

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New Delhi, India, 110029

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Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel, 44281

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

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Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00185

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Nagoya, Aichi, Japan, 467-8602

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Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

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Riga, Latvia

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Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

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Mexico

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Bern, Switzerland, 3010

Genève, Switzerland, 1211

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Birmingham, United Kingdom, B4 7ET

London, United Kingdom, NW1 5QH

Plymouth, United Kingdom, PL6 8BX

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00637377

Submitted Date: November 19, 2009 (v18)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2009

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 19, 2009

Last Update Posted: November 20, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	◉	◉	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 23, 2009 (v17)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: September 2009

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: September 23, 2009

Last Update Posted: September 24, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

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Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
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Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

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- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

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Fukushima, Japan, 960-1295

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Korea, Republic of, Gyeonggi-do

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

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Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

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México D.F., Mexico, 04030

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

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Groningen, Netherlands, 9713 GZ

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Poznan, Poland, 60-355

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

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Ask Contact, Singapore, 168751

Singapore, Singapore, 119074

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Banska Bystrica, Slovakia, 97517

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Spain, La Coruna

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Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Pamplona, Spain, 31008

Sevilla, Spain, 41013

Sevilla, Spain, 41071

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

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London, United Kingdom, NW1 5QH

Plymouth, United Kingdom, PL6 8BX

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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	◉	◉	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 1, 2009 (v16)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: September 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: September 1, 2009

Last Update Posted: September 2, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Active, not recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

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Chatswood, New South Wales, Australia, 2067

[Recruiting]

Sydney, New South Wales, Australia, 2000

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Parkville, Victoria, Australia, 3050

Australia, Western Australia

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[Recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Recruiting]
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Freiburg, Baden-Württemberg, Germany, 79106

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Heidelberg, Baden-Württemberg, Germany, 69120

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Tübingen, Baden-Württemberg, Germany, 72076

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Germany, Niedersachsen

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Essen, Nordrhein-Westfalen, Germany, 45147

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Köln, Nordrhein-Westfalen, Germany, 51109

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Münster, Nordrhein-Westfalen, Germany, 48145

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Kiel, Schleswig-Holstein, Germany, 24105

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Warszawa, Poland, 00-621

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Warszawa, Poland, 03-709

[Recruiting]

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Santiago de Compostela, La Coruna, Spain, 15705

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Alicante, Spain, 03016

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Barcelona, Spain, 08017

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[Recruiting]

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[Recruiting]

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[Recruiting]

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United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]

Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]

Oxford, United Kingdom, OX3 9DU

[Recruiting]

Plymouth, United Kingdom, PL6 8BX

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	◉	◉	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00637377

Submitted Date: July 3, 2009 (v15)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: July 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: July 3, 2009

Last Update Posted: July 7, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]

Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1020

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

[Not yet recruiting]
Marburg, Hessen, Germany, 35043

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Recruiting]

Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]

Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]

Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Recruiting]

Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]

Dresden, Sachsen, Germany, 01067

[Recruiting]

Dresden, Sachsen, Germany, 01307

[Recruiting]

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]

Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Recruiting]
Haifa, Israel, 34362

[Recruiting]

Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Recruiting]
Ancona, Italy, 60020

[Recruiting]
Bari, Italy, 70124

[Recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]

Milano, Italy, 20142

[Not yet recruiting]

Padova, Italy, 35128

[Recruiting]

Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]

Roma, Italy, 00198

[Not yet recruiting]

Siena, Italy, 53100

[Recruiting]

Torino, Italy, 10126

[Recruiting]

Udine, Italy, 33100

[Not yet recruiting]

Varese, Italy, 21100

Japan, Aichi

[Recruiting]

Nagoya, Aichi, Japan, 466-8560

[Recruiting]

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]

Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]

Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Recruiting]

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Recruiting]

Seoul, Korea, Korea, Republic of, 110 744

Korea, Republic of

[Not yet recruiting]

Incheon, Korea, Republic of, 405-760

[Recruiting]

Seoul, Korea, Republic of, 110-744

[Recruiting]

Seoul, Korea, Republic of, 138-736

[Recruiting]

Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]

Riga, Latvia, 1002

[Recruiting]

Riga, Latvia, 1009

Mexico, DF

[Recruiting]

Mexico City, DF, Mexico, 06800

[Not yet recruiting]

Mexico City, DF, Mexico, 14080

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Recruiting]
Chihuahua, Mexico, 31238

[Recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]

Rotterdam, Netherlands, 3015 GD

Poland

[Recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Recruiting]
Porto, Portugal, 4200-319

Singapore

[Recruiting]

Singapore, Singapore, 119074

[Recruiting]

Singapore, Singapore, 159964

[Recruiting]

Singapore, Singapore, 168751

[Recruiting]

Singapore, Singapore, 308433

Slovakia

[Recruiting]

Banska Bystrica, Slovakia, 97517

[Recruiting]

Bratislava, Slovakia, 813 69

Spain, Asturias

[Recruiting]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]

Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]

Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Recruiting]

Alicante, Spain, 03016

[Recruiting]

Barcelona, Spain, 08017

[Recruiting]

Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

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Barcelona, Spain, 08036

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Madrid, Spain, 28002

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Madrid, Spain, 28046

[Recruiting]
Malaga, Spain, 29010

[Recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Recruiting]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

Sweden

[Recruiting]
Linköping, Sweden, 58185

[Recruiting]
Stockholm, Sweden, 11282

[Recruiting]

Örebro, Sweden, 70185

Switzerland

[Recruiting]

Basel, Switzerland, 4031

[Recruiting]

Bern, Switzerland, 3010

[Recruiting]

Genève, Switzerland, 1211

[Recruiting]

Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Terminated]

Manchester, United Kingdom, M13 9PT

[Not yet recruiting]

Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]

Oxford, United Kingdom, OX3 9DU

[Recruiting]

Plymouth, United Kingdom, PL6 8BX

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	◉	◉	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 4, 2009 (v14)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: June 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: June 4, 2009

Last Update Posted: June 5, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]

Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1020

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

[Not yet recruiting]
Marburg, Hessen, Germany, 35043

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]

Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]

Incheon, Korea, Republic of, 405-760

[Not yet recruiting]

Seoul, Korea, Republic of, 110 744

[Recruiting]

Seoul, Korea, Republic of, 138-736

[Not yet recruiting]

Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]

Riga, Latvia, 1002

[Recruiting]

Riga, Latvia, 1009

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Recruiting]
Chihuahua, Mexico, 31238

[Recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]

Lisboa, Portugal, 1649-035

[Recruiting]

Porto, Portugal, 4200-319

Singapore

[Recruiting]

Singapore, Singapore, 119074

[Not yet recruiting]

Singapore, Singapore, 159964

[Recruiting]

Singapore, Singapore, 168751

[Recruiting]

Singapore, Singapore, 308433

Slovakia

[Recruiting]

Banska Bystrica, Slovakia, 97517

[Recruiting]

Bratislava, Slovakia, 813 69

Spain, Asturias

[Recruiting]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]

Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]

Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28046

[Recruiting]
Malaga, Spain, 29010

[Recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

Sweden

[Recruiting]
Linköping, Sweden, 58185

[Recruiting]
Stockholm, Sweden, 11282

[Recruiting]
Örebro, Sweden, 70185

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]

Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
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9	○	○	January 5, 2009	Contacts/Locations and Study Status
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13	◉	◉	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
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17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: May 4, 2009 (v13)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: May 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: May 4, 2009

Last Update Posted: May 5, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]

Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]

Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]

Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]

São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]

Florianopolis, Brazil, 88015-080

[Not yet recruiting]

Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]

Bogota, Colombia

[Terminated]

Bogotá, Colombia

[Recruiting]

Cali, Colombia

[Terminated]

Floridablanca-Santander, Colombia

[Not yet recruiting]

Medellín, Colombia

[Terminated]

Medellín, Colombia

[Recruiting]

Medellín, Colombia

Czech Republic

[Recruiting]

Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Terminated]

Montpellier, France, 34295

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]

Erlangen, Bayern, Germany, 91054

[Recruiting]

München, Bayern, Germany, 81675

[Not yet recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]

Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

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Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]

Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]

Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]
Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]
Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]

Wroclaw, Poland, 50-368

Portugal

[Recruiting]

Coimbra, Portugal, 3000-548

[Not yet recruiting]

Lisboa, Portugal, 1649-035

[Not yet recruiting]

Porto, Portugal, 4200- 319

Singapore

[Recruiting]

ask Contact, Singapore, 168751

[Not yet recruiting]

Singapore, Singapore, 119074

[Not yet recruiting]

Singapore, Singapore, 159964

[Not yet recruiting]

Singapore, Singapore, 308433

Slovakia

[Recruiting]

Banska Bystrica, Slovakia, 97517

[Recruiting]

Bratislava, Slovakia, 813 69

[Terminated]

Martin, Slovakia, 036 59

[Terminated]

Zilina, Slovakia, 012 07

Spain, Asturias

[Recruiting]

Oviedo, Asturias, Spain, 33012

[Terminated]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]

Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]

Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]

Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]

Alicante, Spain, 03016

[Recruiting]

Barcelona, Spain, 08017

[Not yet recruiting]

Barcelona, Spain, 08022

[Not yet recruiting]

Barcelona, Spain, 08035

[Terminated]

Barcelona, Spain, 08035

[Not yet recruiting]

Barcelona, Spain, 08036

[Terminated]

Bilbao, Spain, 48006

[Recruiting]
Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]
Jönköping, Sweden, 551 85

[Recruiting]
Linköping, Sweden, 58185

[Terminated]
Luleå, Sweden, 97180

[Recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	◉	◉	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 2, 2009 (v12)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: April 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: April 2, 2009

Last Update Posted: April 3, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]

Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]

Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]

Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]

São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]

Florianopolis, Brazil, 88015-080

[Not yet recruiting]

Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]

Bogota, Colombia

[Terminated]

Bogotá, Colombia

[Recruiting]

Cali, Colombia

[Terminated]

Floridablanca-Santander, Colombia

[Not yet recruiting]

Medellín, Colombia

[Terminated]

Medellín, Colombia

[Recruiting]

Medellín, Colombia

Czech Republic

[Recruiting]

Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Terminated]

Montpellier, France, 34295

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]

Erlangen, Bayern, Germany, 91054

[Recruiting]

München, Bayern, Germany, 81675

[Not yet recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]

Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]

Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]

Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]

Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]

Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]

Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]

Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]

Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]

Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]

Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]

Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

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Kfar Saba, Israel, 44281

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Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

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Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

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Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

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Milano, Italy, 20142

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Milano, Italy, 20142

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Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]

Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]

Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]
Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]

Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Recruiting]

México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]

Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]

Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]

Wroclaw, Poland, 50-368

Portugal

[Recruiting]

Coimbra, Portugal, 3000-548

[Not yet recruiting]

Lisboa, Portugal, 1649-035

[Not yet recruiting]

Porto, Portugal, 4200- 319

Singapore

[Recruiting]

ask Contact, Singapore, 168751

[Not yet recruiting]

Singapore, Singapore, 119074

[Not yet recruiting]

Singapore, Singapore, 159964

[Not yet recruiting]

Singapore, Singapore, 308433

Slovakia

[Recruiting]

Banska Bystrica, Slovakia, 97517

[Recruiting]

Bratislava, Slovakia, 813 69

[Terminated]

Martin, Slovakia, 036 59

[Terminated]

Zilina, Slovakia, 012 07

Spain, Asturias

[Recruiting]

Oviedo, Asturias, Spain, 33012

[Terminated]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]

Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]

Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]

Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]

Alicante, Spain, 03016

[Recruiting]

Barcelona, Spain, 08017

[Not yet recruiting]

Barcelona, Spain, 08022

[Not yet recruiting]

Barcelona, Spain, 08035

[Terminated]

Barcelona, Spain, 08035

[Not yet recruiting]

Barcelona, Spain, 08036

[Terminated]

Bilbao, Spain, 48006

[Recruiting]
Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

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Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

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Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

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Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]
Jönköping, Sweden, 551 85

[Recruiting]
Linköping, Sweden, 58185

[Terminated]
Luleå, Sweden, 97180

[Recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	◉	◉	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 5, 2009 (v11)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: March 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: March 5, 2009

Last Update Posted: March 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]

Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]

Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]
Florianopolis, Brazil, 88015-080

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Terminated]
Bogotá, Colombia

[Recruiting]
Cali, Colombia

[Terminated]
Floridablanca-Santander, Colombia

[Not yet recruiting]
Medellín, Colombia

[Terminated]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Terminated]

Montpellier, France, 34295

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]

Erlangen, Bayern, Germany, 91054

[Recruiting]

München, Bayern, Germany, 81675

[Not yet recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]

Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]

Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Recruiting]

México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]

Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]

Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]

Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Terminated]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]
Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Terminated]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Terminated]
Bilbao, Spain, 48006

[Not yet recruiting]

Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]

Jönköping, Sweden, 551 85

[Not yet recruiting]

Linköping, Sweden, 58185

[Terminated]

Luleå, Sweden, 97180

[Not yet recruiting]

Stockholm, Sweden, 11282

[Terminated]

Uppsala, Sweden, 75185

[Terminated]

Västerås, Sweden, 721 89

[Not yet recruiting]

Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]

Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]

Basel, Switzerland, 4031

[Not yet recruiting]

Bern, Switzerland, 3010

[Not yet recruiting]

Genève, Switzerland, 1211

[Recruiting]

Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

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References

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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	◉	◉	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 5, 2009 (v10)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: February 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: February 5, 2009

Last Update Posted: February 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]

Chatswood, New South Wales, Australia, 2067

[Terminated]

Sydney, New South Wales, Australia, 2000

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]

Bedford Park, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Terminated]
Florianopolis, Brazil, 88015-080

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Terminated]
Bogotá, Colombia

[Recruiting]
Cali, Colombia

[Terminated]
Floridablanca-Santander, Colombia

[Not yet recruiting]
Medellín, Colombia

[Terminated]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Not yet recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Terminated]

Montpellier, France, 34295

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]

Erlangen, Bayern, Germany, 91054

[Recruiting]

München, Bayern, Germany, 81675

[Not yet recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]

Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]

Kolkata, India, 700073

[Recruiting]

Mumbai, India, 400 050

[Not yet recruiting]

New Delhi, India, 110002

[Recruiting]

New Delhi, India, 110029

[Recruiting]

Orissa, India, 751 024

Israel

[Recruiting]

Afula, Israel, 18101

[Not yet recruiting]

Beer Sheva, Israel, 84101

[Not yet recruiting]

Haifa, Israel, 34362

[Recruiting]

Jerusalem, Israel, 91120

[Not yet recruiting]

Kfar Saba, Israel, 44281

[Recruiting]

Petach Tikva, Israel, 49100

[Recruiting]

Rehovot, Israel, 76100

[Recruiting]

Tel Aviv, Israel, 64239

[Recruiting]

Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]
Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]

Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]

Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]

Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]

Alicante, Spain, 03016

[Not yet recruiting]

Barcelona, Spain, 08017

[Not yet recruiting]

Barcelona, Spain, 08022

[Not yet recruiting]

Barcelona, Spain, 08035

[Terminated]

Barcelona, Spain, 08035

[Not yet recruiting]

Barcelona, Spain, 08036

[Terminated]

Bilbao, Spain, 48006

[Not yet recruiting]

Madrid, Spain, 28002

[Not yet recruiting]

Madrid, Spain, 28040

[Not yet recruiting]

Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]

Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Terminated]

Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

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Scroll up to access the controls Scroll to the Study top

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	◉	◉	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: January 5, 2009 (v9)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	January 2009
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	July 2011 [Anticipated]
Study Completion:	July 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	January 5, 2009
Last Update Posted:	January 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Not yet recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]

Chatswood, New South Wales, Australia, 2067

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1020

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1070

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Not yet recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]

Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]

Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]

Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]

Dresden, Sachsen, Germany, 01067

[Not yet recruiting]

Dresden, Sachsen, Germany, 01307

[Recruiting]

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]

Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]

Berlin, Germany, 12200

[Recruiting]

Hamburg, Germany, 20251

Hungary

[Recruiting]

Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Not yet recruiting]

Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]

Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

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Milano, Italy, 20142

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Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]

Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]

Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Recruiting]

México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]

Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]

Groningen, Netherlands, 9713 GZ

[Not yet recruiting]

Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]

Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

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Barcelona, Spain, 08035

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Barcelona, Spain, 08036

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Madrid, Spain, 28002

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Madrid, Spain, 28040

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Madrid, Spain, 28046

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Malaga, Spain, 29010

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Pamplona, Spain, 31008

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Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

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Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

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References

Citations:

Links:

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	◉	◉	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: December 1, 2008 (v8)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	December 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	July 2011 [Anticipated]
Study Completion:	July 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	December 1, 2008
Last Update Posted:	December 2, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Not yet recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]

Chatswood, New South Wales, Australia, 2067

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1070

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]

München, Bayern, Germany, 81675

[Not yet recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]

Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]

Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]

Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]

Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]

Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]

Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Not yet recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]

Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

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Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]

Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

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Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]

Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

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Citations:

Links:

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Scroll up to access the controls

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
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28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00637377

Submitted Date: November 4, 2008 (v7)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2008

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: September 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 4, 2008

Last Update Posted: November 5, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]

San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]

Buenos Aires, Argentina

[Not yet recruiting]

Córdoba, Argentina, X5000IIT

[Not yet recruiting]

Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]

Chatswood, New South Wales, Australia, 2067

[Recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1070

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Not yet recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]

Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]

Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]

Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	◉	◉	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: October 2, 2008 (v6)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25
311523
VIEW 2

Study Status

Record Verification: October 2008

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: September 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: October 2, 2008

Last Update Posted: October 3, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Not yet recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Not yet recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Not yet recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Not yet recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Not yet recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Not yet recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Not yet recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]

Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

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[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

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Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]

Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

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Barcelona, Spain, 08035

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Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

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Madrid, Spain, 28046

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Malaga, Spain, 29010

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Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

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Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]

Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Not yet recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Grampian

[Not yet recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Not yet recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Not yet recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 2374

Samsung Bioepis Exhibit 1017, pg. 2374

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	◉	◉	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 26, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 30, 2008 (v5)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2)

Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	September 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	April 2008 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	September 30, 2008
Last Update Posted:	October 1, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm^2, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Not yet recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Not yet recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Not yet recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Not yet recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Not yet recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Not yet recruiting]
Hamburg, Germany, 20251

Hungary

[Not yet recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1082

[Not yet recruiting]
Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]

Bangalore, India, 560010

[Not yet recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Not yet recruiting]

Kolkata, India, 700073

[Not yet recruiting]

Mumbai, India, 400 050

[Recruiting]

New Delhi, India, 110029

[Not yet recruiting]

Orissa, India, 751 024

Israel

[Not yet recruiting]

Afula, Israel, 18101

[Recruiting]

Jerusalem, Israel, 91120

[Recruiting]

Petach Tikva, Israel, 49100

[Not yet recruiting]

Rehovot, Israel, 76100

[Recruiting]

Tel Aviv, Israel, 64239

[Not yet recruiting]

Tel Hashomer, Israel, 52621

[Recruiting]

Zerifin, Israel, 70300

Italy

[Not yet recruiting]

Ancona, Italy, 60020

[Not yet recruiting]

Bari, Italy, 70124

[Not yet recruiting]

Catania, Italy

[Not yet recruiting]

Firenze, Italy, 50139

[Not yet recruiting]

Genova, Italy, 16132

[Not yet recruiting]

Milano, Italy, 20132

[Not yet recruiting]

Milano, Italy, 20142

[Not yet recruiting]

Padova, Italy, 35128

[Not yet recruiting]

Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 61-848

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 01-755

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]
Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]

Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Not yet recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

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U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	◉	◉	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 26, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: August 4, 2008 (v4)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	August 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	September 2011 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	August 4, 2008
Last Update Posted:	August 5, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: (ex US: +1) 1-888-842-2937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]

San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]

Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg / 274

[Recruiting]
Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

[Not yet recruiting]
Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

[Not yet recruiting]
Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

[Not yet recruiting]
München, Bayern / 280, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

[Not yet recruiting]
Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

[Not yet recruiting]
Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

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Köln, Nordrhein-Westfalen / 297, Germany, 50931

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Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

[Not yet recruiting]
Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

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Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

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Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

[Not yet recruiting]
Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Rheinland-Pfalz / 381

[Not yet recruiting]
Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

[Not yet recruiting]
Dresden, Sachsen / 313, Germany, 01067

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Dresden, Sachsen / 313, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

[Not yet recruiting]
Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

[Not yet recruiting]
Budapest, Hungary, 1036

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Budapest, Hungary, 1082

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Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Not yet recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

[Not yet recruiting]

Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Petach Tikva, Israel, 49100

[Not yet recruiting]
Rehovot, Israel, 76100

[Not yet recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Not yet recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]

Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

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Milano, Italy, 20132

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Milano, Italy, 20142

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Padova, Italy, 35128

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Roma, Italy, 00133

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Roma, Italy, 00168

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Roma, Italy, 00198

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Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
ask Contact, Tokyo, Japan, 101-8309

[Not yet recruiting]
ask Contact, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Not yet recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

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Riga, Latvia, 1009

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Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

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México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

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Groningen, Netherlands, 9713 GZ

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Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

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Gdansk, Poland, 80-952

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Katowice, Poland, 40-760

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Poznan, Poland, 61-848

[Not yet recruiting]
Warszawa, Poland, 00-416

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Warszawa, Poland, 00-621

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Warszawa, Poland, 01-755

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Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]

Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

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Santiago de Compostela, La Coruna, Spain, 15706

Spain

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Alicante, Spain, 03016

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Barcelona, Spain, 08017

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Barcelona, Spain, 08036

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Pamplona, Spain, 31008

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Sevilla, Spain, 41013

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Valencia, Spain, 46014

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Valladolid, Spain, 47005

Sweden

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Jönköping, Sweden, 551 85

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Linköping, Sweden, 58185

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Luleå, Sweden, 97180

[Not yet recruiting]
Örebro, Sweden, 70185

[Not yet recruiting]
Stockholm, Sweden, 11282

Switzerland, Basel / 633

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Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

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Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

[Not yet recruiting]

Zürich, Zürich / 633, Switzerland, 8091

Switzerland

[Not yet recruiting]

Bern, Switzerland, 3010

United Kingdom, Devon

[Not yet recruiting]

Torquay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Not yet recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

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Available IPD/Information:

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	◉	◉	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status
21	O	O	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 26, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 19, 2008 (v3)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	June 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	June 19, 2008
Last Update Posted:	June 20, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: (ex US: +1) 1-888-842-2937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]

Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]

East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Not yet recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]

Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Not yet recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

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Marseille, France, 13008

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Nantes Cedex, France, 44035

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Paris, France, 75015

Germany, Baden-Württemberg / 274

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Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

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Germany, Baden-Württemberg / 277

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Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

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München, Bayern / 280, Germany, 81675

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Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

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Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

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Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

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Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

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Köln, Nordrhein-Westfalen / 297, Germany, 50931

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Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

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Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

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Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

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Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

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Germany, Rheinland-Pfalz / 381

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Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

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Dresden, Sachsen / 313, Germany, 01067

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Dresden, Sachsen / 313, Germany, 01307

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Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

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Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

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Budapest, Hungary, 1036

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Budapest, Hungary, 1082

[Not yet recruiting]
Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Not yet recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Not yet recruiting]
Chennai, Tamil Nadu, India, 600 006

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Coimbatore, Tamil Nadu, India, 641014

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Madurai, Tamil Nadu, India, 625 020

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Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

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Chandigarh, India, 160062

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Gugarat, India

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Hyderabad, India, 500 034

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Kerala, India, 683572

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Kolkata, India, 700073

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[Not yet recruiting]
New Delhi, India, 110029

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Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

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Jerusalem, Israel, 91120

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Petach Tikva, Israel, 49100

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Rehovot, Israel, 76100

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Tel Aviv, Israel, 64239

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Tel Hashomer, Israel, 52621

[Not yet recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

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Catania, Italy

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Firenze, Italy, 50139

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Genova, Italy, 16132

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Milano, Italy, 20132

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Siena, Italy, 53100

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Torino, Italy, 10126

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Trieste, Italy, 34100

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Udine, Italy, 33100

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Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

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Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

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Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

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Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

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Kita, Kagawa, Japan, 761-0793

Japan, Osaka

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Hirakata, Osaka, Japan, 573-1191

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Suita, Osaka, Japan, 565-0871

Japan, Shiga

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Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
ask Contact, Tokyo, Japan, 101-8309

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Not yet recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]

Kagoshima, Japan, 890-8520

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Kyoto, Japan, 606-8507

[Not yet recruiting]
Tokyo, Japan, 160-8582

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

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Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

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Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

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Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

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Monterrey, Nuevo Leon, Mexico, 64460

Mexico

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Chihuahua, Mexico, 31238

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Mexico City, Mexico, 06030

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México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

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Nijmegen, EX, Netherlands, 6525

Netherlands

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Groningen, Netherlands, 9713 GZ

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Leiden, Netherlands, 2333 ZA

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Rotterdam, Netherlands, 3015 GD

Poland

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Gdansk, Poland, 80-952

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Katowice, Poland, 40-760

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Poznan, Poland, 61-848

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Warszawa, Poland, 00-416

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Warszawa, Poland, 02-005

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Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]
Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

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Santiago de Compostela, La Coruna, Spain, 15706

Spain

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Alicante, Spain, 03016

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Barcelona, Spain, 08017

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Valencia, Spain, 46014

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Valladolid, Spain, 47005

Sweden

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Luleå, Sweden, 97180

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Örebro, Sweden, 70185

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Stockholm, Sweden, 11282

Switzerland, Basel / 633

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Switzerland, Genève / 633

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Switzerland, Zürich / 633

[Not yet recruiting]
Zürich, Zürich / 633, Switzerland, 8091

Switzerland

[Not yet recruiting]

Bern, Switzerland, 3010

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Not yet recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

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Citations:

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	◉	◉	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status
21	O	O	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 26, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 24, 2008 (v2)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	April 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	April 24, 2008
Last Update Posted:	April 25, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: +1-888-84 22937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Córdoba

[Not yet recruiting]

Córdoba, Córdoba, Argentina, X5000IIT

Argentina, Santa Fe

[Not yet recruiting]

Rosario, Santa Fe, Argentina, S2000ANJ

Australia, New South Wales

[Not yet recruiting]

Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Not yet recruiting]

East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]

Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Not yet recruiting]

Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Not yet recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]

Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

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Bogota, Colombia

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Cali, Colombia

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Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

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Lyon, France, 69003

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Lyon, France, 69006

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Marseille, France, 13008

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Nantes Cedex, France, 44035

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Paris, France, 75015

Germany, Baden-Württemberg / 274

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Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

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Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

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Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

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München, Bayern / 280, Germany, 81675

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Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

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Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

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Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

[Not yet recruiting]

Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

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Köln, Nordrhein-Westfalen / 297, Germany, 50931

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Germany, Nordrhein-Westfalen / 298

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Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

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Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

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Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

[Not yet recruiting]

Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Rheinland-Pfalz / 381

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Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

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Dresden, Sachsen / 313, Germany, 01067

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Dresden, Sachsen / 313, Germany, 01307

[Not yet recruiting]

Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

[Not yet recruiting]

Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

[Not yet recruiting]

Budapest, Hungary, 1036

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Budapest, Hungary, 1082

[Not yet recruiting]

Budapest, Hungary, 1106

[Not yet recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Not yet recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Not yet recruiting]
Chennai, Tamil Nadu, India, 600 006

[Not yet recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Not yet recruiting]
Madurai, Tamil Nadu, India, 625 020

[Not yet recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Not yet recruiting]
Gujarat, India

[Not yet recruiting]
Hyderabaad, India, 500 034

[Not yet recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

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New Delhi, India, 110029

[Not yet recruiting]

Orissa, India, 751 024

Israel

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Afula, Israel, 18101

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Jerusalem, Israel, 91120

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Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

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Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

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Maebashi, Gunma, Japan, 371-8511

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Sapporo, Hokkaido, Japan, 060-8604

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Latvia

[Not yet recruiting]
Riga, Latvia, 1002

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Riga, Latvia, 1009

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Riga, Latvia

Mexico, DF

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[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

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Netherlands, EX

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Nijmegen, EX, Netherlands, 6525

Netherlands

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Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

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Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
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Poznan, Poland, 61-848

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Warszawa, Poland, 00-416

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Wroclaw, Poland, 50-368

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Lisboa, Portugal, 1649-035

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Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

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Bratislava, Slovakia, 81369

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Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
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[Not yet recruiting]
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Spain, Madrid

[Not yet recruiting]
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Spain

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Sevilla, Spain, 41071

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Valencia, Spain, 46014

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Valencia, Spain, 46015

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Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

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Luleå, Sweden, 97180

[Not yet recruiting]
Örebro, Sweden, 70185

[Not yet recruiting]
Stockholm, Sweden, 11282

Switzerland, Basel / 633

[Not yet recruiting]
Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

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[Not yet recruiting]
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History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
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10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	O	O	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	O	O	November 19, 2009	Study Status
19	O	O	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	O	O	July 9, 2010	Contacts/Locations and Study Status
21	O	O	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
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24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 26, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 17, 2008 (v1)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	March 2008
Overall Status:	Not yet recruiting
Study Start:	March 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	March 17, 2008
Last Update Posted:	March 18, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options \\
Telephone: +1-888-84 22937

Study Officials: Study Director Bayer Study Manager
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1120AAN

Buenos Aires, Capital Federal, Argentina, C1122AAI

Argentina, Córdoba

Córdoba, Córdoba, Argentina, X5000IIT

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, 1288

Argentina

Buenos Aires, Argentina, C1181ACH

Australia, New South Wales

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Steiermark / 632

Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

Innsbruck, Tirol / 632, Austria, 6020

Austria

Linz, Austria, 4021

Salzburg, Austria, 5020

Wien, Austria, 1090

Belgium

Bruxelles, Belgium, 1070

Liege, Belgium, 4000

Brazil, Centro-oeste

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Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

Brazil

Belo Horizonte, Brazil, 30150-270

Sao Paulo, Brazil, 05651-901

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 63400

Hradec Kralove, Czech Republic, 500 05

Olomouc, Czech Republic, 775 20

Praha 4, Czech Republic, 14000

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France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Grenoble, France, 38043

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris, France, 75015

Germany, Baden-Württemberg / 274

Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

Erlangen, Bayern / 280, Germany, 91054

München, Bayern / 280, Germany, 81675

Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

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Köln, Nordrhein-Westfalen / 297, Germany, 50931

Köln, Nordrhein-Westfalen / 297, Germany, 50996

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Budapest, Hungary, 1106

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Madurai, Tamil Nadu, India, 625 020

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Roma, Italy, 00168

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Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Tokyo, Japan, 101-8309

Tokyo, Japan, 160-8582

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Riga, Latvia, 1002

Riga, Latvia, 1009

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Mexico City, DF, Mexico, 06800

Mexico City, DF, Mexico, 14080

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Monterrey, Nuevo Leon, Mexico, 64460

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Mexico, D.F., Mexico, 04030

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Torquay, United Kingdom, TQ2 7AA

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

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Study Record Versions

Version	A	B	Submitted Date	Changes

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Version	A	B	Submitted Date	Changes
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24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	◉	◉	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 28, 2014 (v30)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: November 2014

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	November 28, 2014
Last Update Posted:	December 12, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	Sponsor
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
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Locations: **Argentina, Ciudad Auton. de Buenos Aires**

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IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

[Study Results] Schmidt-Erfurth U, Kaiser PK, Korobelnik JF, Brown DM, Chong V, Nguyen QD, Ho AC, Ogura Y, Simader C, Jaffe GJ, Slakter JS, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Sowade O, Zeitz O, Norenberg C, Sandbrink R, Heier JS. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. Ophthalmology. 2014 Jan;121(1):193-201. doi: 10.1016/j.ophtha.2013.08.011. Epub 2013 Sep 29. PubMed 24084500

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

URL: http://www.clinicaltrialsregister.eu/
Description: Click here to find information about studies related to Bayer Healthcare products conducted in Europe

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree [A*]	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration [A*]	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract [A*]	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation [A*]	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage [A*]	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia [A*]	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
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History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 2569

Samsung Bioepis Exhibit 1017, pg. 2569

Version	A	B	Submitted Date	Changes
1	O	O	March 17, 2008	None (earliest Version on record)
2	O	O	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	O	O	June 19, 2008	Contacts/Locations and Study Status
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	◉	◉	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 25, 2014 (v29)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: April 2014

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	April 25, 2014
Last Update Posted:	May 8, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	Sponsor
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

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Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

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Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

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Linz, Austria, 4021

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London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

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IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

[Study Results] Schmidt-Erfurth U, Kaiser PK, Korobelnik JF, Brown DM, Chong V, Nguyen QD, Ho AC, Ogura Y, Simader C, Jaffe GJ, Slakter JS, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Sowade O, Zeitz O, Norenberg C, Sandbrink R, Heier JS. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. Ophthalmology. 2014 Jan;121(1):193-201. doi: 10.1016/j.ophtha.2013.08.011. Epub 2013 Sep 29. PubMed 24084500

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree [A*]	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration [A*]	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract [A*]	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation [A*]	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage [A*]	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia [A*]	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
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Scroll up to access the controls

Scroll to the Study top

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ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 2643

Samsung Bioepis Exhibit 1017, pg. 2643

Version	A	B	Submitted Date	Changes
1	O	O	March 17, 2008	None (earliest Version on record)
2	O	O	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	O	O	June 19, 2008	Contacts/Locations and Study Status
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	◉	◉	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 12, 2013 (v28)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: March 2013

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	March 12, 2013
Last Update Posted:	March 15, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

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Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree [A*]	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration [A*]	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract [A*]	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation [A*]	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage [A*]	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia [A*]	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls

Scroll to the Study top

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Mylan Exhibit 1017
Mylan v. Regeneron, IPR2022-01226
Page 2717

Samsung Bioepis Exhibit 1017, pg. 2717

Version	A	B	Submitted Date	Changes
1	O	O	March 17, 2008	None (earliest Version on record)
2	O	O	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	O	O	June 19, 2008	Contacts/Locations and Study Status
4	O	O	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	O	O	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	O	O	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	O	O	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	O	O	December 1, 2008	Study Status and Contacts/Locations
9	O	O	January 5, 2009	Contacts/Locations and Study Status
10	O	O	February 5, 2009	Contacts/Locations and Study Status
11	O	O	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	O	O	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	O	O	May 4, 2009	Study Status
14	O	O	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	O	O	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	O	O	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	◉	◉	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 27, 2012 (v27)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: February 2012

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	February 27, 2012
Last Update Posted:	February 28, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

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Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

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Linz, Austria, 4021

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Barcelona, Spain, 08036

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Zürich, Switzerland, 8091

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London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1

Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
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Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants	291	309	296	306	1202

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation)	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/291 (12.37%)	50/309 (16.18%)	42/297 (14.14%)	50/307 (16.29%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	1/307 (0.33%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac failure [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	3/307 (0.98%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Eye disorders				
Cataract (Fellow Eye) [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cataract (Study Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cataract cortical (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation (Fellow Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hyphaema (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Macular cyst (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Fellow Eye) [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Macular hole (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Maculopathy (Fellow Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification (Study Eye) [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal detachment (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Retinal haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal haemorrhage (Study Eye) [A*]	1/291 (0.34%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epithelial tear (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epitheliopathy (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal pigment epitheliopathy (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced (Fellow Eye) [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)
Visual acuity reduced (Study Eye) [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	5/307 (1.63%)
Vitreous haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Colitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
General disorders				
Chest pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Hepatobiliary disorders				
Cholecystitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pneumonia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	2/307 (0.65%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urinary tract infection [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Fall [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Lumbar vertebral fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Upper limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Metabolism and nutrition disorders				
Dehydration [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Syncope [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Renal failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Rash [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cataract operation [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	208/291 (71.48%)	209/309 (67.64%)	209/297 (70.37%)	217/307 (70.68%)
Cardiac disorders				
Atrioventricular block first degree [A*]	12/291 (4.12%)	22/309 (7.12%)	18/297 (6.06%)	17/307 (5.54%)
Eye disorders				
Cataract (Study Eye) [A*]	14/291 (4.81%)	17/309 (5.5%)	12/297 (4.04%)	13/307 (4.23%)
Choroidal neovascularisation (Fellow Eye) [A*]	14/291 (4.81%)	14/309 (4.53%)	15/297 (5.05%)	17/307 (5.54%)
Conjunctival haemorrhage (Study Eye) [A*]	23/291 (7.9%)	24/309 (7.77%)	37/297 (12.46%)	30/307 (9.77%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Detachment of retinal pigment epithelium (Study Eye) [A*]	26/291 (8.93%)	26/309 (8.41%)	24/297 (8.08%)	25/307 (8.14%)
Eye pain (Study Eye) [A*]	27/291 (9.28%)	33/309 (10.68%)	22/297 (7.41%)	21/307 (6.84%)
Macular cyst (Study Eye) [A*]	15/291 (5.15%)	6/309 (1.94%)	7/297 (2.36%)	6/307 (1.95%)
Macular degeneration (Fellow Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	25/297 (8.42%)	33/307 (10.75%)
Macular degeneration (Study Eye) [A*]	27/291 (9.28%)	28/309 (9.06%)	27/297 (9.09%)	33/307 (10.75%)
Ocular hyperaemia (Study Eye) [A*]	18/291 (6.19%)	13/309 (4.21%)	13/297 (4.38%)	9/307 (2.93%)
Retinal cyst (Study Eye) [A*]	10/291 (3.44%)	16/309 (5.18%)	14/297 (4.71%)	11/307 (3.58%)
Retinal degeneration (Study Eye) [A*]	23/291 (7.9%)	27/309 (8.74%)	20/297 (6.73%)	18/307 (5.86%)
Retinal haemorrhage (Fellow Eye) [A*]	21/291 (7.22%)	17/309 (5.5%)	12/297 (4.04%)	21/307 (6.84%)
Retinal haemorrhage (Study Eye) [A*]	39/291 (13.4%)	41/309 (13.27%)	39/297 (13.13%)	37/307 (12.05%)
Retinal oedema (Study Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	14/297 (4.71%)	23/307 (7.49%)
Retinal pigment epitheliopathy (Study Eye) [A*]	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	24/307 (7.82%)
Visual acuity reduced (Fellow Eye) [A*]	10/291 (3.44%)	10/309 (3.24%)	13/297 (4.38%)	19/307 (6.19%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Visual acuity reduced (Study Eye) A*	19/291 (6.53%)	25/309 (8.09%)	33/297 (11.11%)	30/307 (9.77%)
Vitreous detachment (Study Eye) A*	10/291 (3.44%)	19/309 (6.15%)	10/297 (3.37%)	15/307 (4.89%)
General disorders				
Pyrexia A*	9/291 (3.09%)	7/309 (2.27%)	15/297 (5.05%)	5/307 (1.63%)
Infections and infestations				
Influenza A*	8/291 (2.75%)	14/309 (4.53%)	8/297 (2.69%)	17/307 (5.54%)
Nasopharyngitis A*	28/291 (9.62%)	15/309 (4.85%)	26/297 (8.75%)	19/307 (6.19%)
Investigations				
Intraocular pressure increased A*	23/291 (7.9%)	30/309 (9.71%)	21/297 (7.07%)	22/307 (7.17%)
Nervous system disorders				
Headache A*	12/291 (4.12%)	9/309 (2.91%)	12/297 (4.04%)	17/307 (5.54%)
Vascular disorders				
Hypertension A*	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	19/307 (6.19%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

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U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
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- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	◉	◉	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: May 2, 2011 (v14)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	December 2009 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Certification/Extension First Submitted:	April 19, 2011
Certification/Extension First Submitted that Met QC Criteria:	May 2, 2011

Certification/Extension First Posted:	May 5, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	May 2, 2011
Last Update Posted:	May 5, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 5

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: macular laser therapy laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness

Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director

Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

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History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

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3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
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9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	◉	◉	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

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Study NCT00789477

Submitted Date: January 24, 2011 (v13)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	January 2011
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	September 2010 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	January 24, 2011
Last Update Posted:	January 26, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	◉	◉	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: November 18, 2010 (v12)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	November 2010
Overall Status:	Active, not recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	November 18, 2010
Last Update Posted:	November 19, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

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Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

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Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

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Nashville, Tennessee, United States, 37203