

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
28	☐	☐	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status and References
29	☐	☐	April 25, 2014	Sponsor/Collaborators, Study Status, Baseline Characteristics and References
30	☐	☐	November 28, 2014	Study Status 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 March 17, 2008

Met QC Criteria:

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that March 17, 2008

Met QC Criteria:

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
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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

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Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris, France, 75015

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Erlangen, Bayern / 280, Germany, 91054

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Kiel, Schleswig-Holstein / 306, Germany, 24105

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Budapest, Hungary, 1106

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Roma, Italy, 00168

Roma, Italy, 00198

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Torino, Italy, 10126

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Nagoya, Aichi, Japan, 467-8602

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Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

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Kagoshima, Japan, 890-8520

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