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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

- 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

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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

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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

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	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:	

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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

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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.

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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**

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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

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Linz, Austria, 4021

Salzburg, Austria, 5020

Wien, Austria, 1090

Belgium

Bruxelles, Belgium, 1070

Liege, Belgium, 4000

Brazil, Centro-oeste

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

Londrina, Paraná, Brazil, 86038440

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

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Praha 4, Czech Republic, 14000

France, Cedex 12

Paris, Cedex 12, France, 75557

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

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Heidelberg, Baden-Württemberg / 275, Germany, 69112

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Germany, Berlin / 285

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Berlin, Berlin / 285, Germany, 12200

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Germany, Nordrhein-Westfalen / 297

Köln, Nordrhein-Westfalen / 297, Germany, 50931

Köln, Nordrhein-Westfalen / 297, Germany, 50996

Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

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Germany, Nordrhein-Westfalen / 320

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Germany, Nordrhein-Westfalen / 321

Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Nordrhein-Westfalen / 504

Duisburg, Nordrhein-Westfalen / 504, Germany, 47119

Germany, Rheinland-Pfalz / 381

Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

Dresden, Sachsen / 313, Germany, 01307

Leipzig, Sachsen / 313, Germany, 04103

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Germany, Schleswig-Holstein / 306

Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1082

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

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Bangalore, India, 560010

Chandigarh, India, 160062

Gujarat, India

Hyderabaad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400031

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel, 18101

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Jerusalem, Israel, 91120

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

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Bari, Italy, 70124

Catania, Italy

Firenze, Italy, 50139

Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Siena, Italy, 53100

Torino, Italy, 10126

Trieste, Italy, 34100

Udine, Italy, 33100

Varese, Italy, 21100

Japan, Aichi

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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

Kida, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Tokyo, Japan, 101-8309

Tokyo, Japan, 160-8582

Latvia

Riga, Latvia, 1002

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Riga, Latvia, 1009

Riga, Latvia

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico City, DF, Mexico, 14080

Mexico, Estado de México

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

Mexico, D.F., Mexico, 04030

Netherlands, DD

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

Eindhoven, Noord Brabant, Netherlands, 5623 EJ

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Groningen, Netherlands, 9713 GZ

Leiden, Netherlands, 2333 ZA

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Rotterdam, Netherlands, 3015 GD

Poland

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszawa, Poland, 00-416

Warszawa, Poland, 00-621

Warszawa, Poland, 01-755

Warszawa, Poland, 02-005

Warszawa, Poland, 03-709

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Lisboa, Portugal, 1649-035

Porto, Portugal, 4200- 319

Slovakia

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Bratislava, Slovakia, 81369

Martin, Slovakia, 03659

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Santiago de Compostela, La Coruna, Spain, 15706

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Spain, Madrid

Aravaca, Madrid, Spain, 28023

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28040

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

Jönköping, Sweden, 551 85

Linköping, Sweden, 58185

Luleå, Sweden, 97180

Örebro, Sweden, 70185

Stockholm, Sweden, 11282

Switzerland, Basel / 633

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Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

Zürich, Zürich / 633, Switzerland, 8091

Switzerland

Bern, Switzerland, 3010

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United Kingdom, Northern Ireland

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Manchester, United Kingdom, M13 9PT

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Newcastle upon Tyne, United Kingdom, NE1 4LP

Oxford, United Kingdom, OX3 9DU

Plymouth, United Kingdom, PL6 8BX

Torquay, United Kingdom, TQ2 7AA

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