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Internet Archive
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AFFIDAVIT OF DUNCAN HALL

1. I am a Records Request Processor at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browseable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit A are true and accurate copies of printouts of screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

7. I declare under penalty of perjury that the foregoing is true and correct.

DATE: 01/27/2021

Duncan Hall

Duncan Hall

EXHIBIT A

https://web.archive.org/web/20090813064936/https://clinicaltrials.gov/ct2/show/NCT00637377

INTERNET ARCHIVE WayBackMachine https://clinicaltrials.gov/ct2/show/NCT00637377 Go MAY AUG SEP 13 2008 2009 2010 21 captures 18 Jan 2009 - 23 Jan 2017 About this capture

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

This study is currently recruiting participants.
Verified by Bayer, July 2009

First Received: March 12, 2008 Last Updated: July 3, 2009 History of Changes

Sponsored by:	**Bayer**
Information provided by:	Bayer
ClinicalTrials.gov Identifier:	NCT00637377

Purpose

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.

Condition	Intervention	Phase
Macular Degeneration	Drug: VEGF Trap-Eye Drug: Ranibizumab	Phase III

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Active Control, Parallel Assignment, Safety/Efficacy Study

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).

Resource links provided by NLM:

Genetics Home Reference related topics: X-linked juvenile retinoschisis

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Ranibizumab Aflibercept

U.S. FDA Resources

Further study details as provided by Bayer:

Primary Outcome Measures:

- 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) [Time Frame: week 52] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52 [Time Frame: week 52] [Designated as safety issue: Yes]
- The proportion of subjects who gain at least 15 letters of vision at Week 52 [Time Frame: week 52] [Designated as safety issue: No]
- Mean change from baseline in total NEI VFQ-25 score at Week 52 [Time Frame: week 52] [Designated as safety issue: No]
- Mean change from baseline in CNV area at Week 52 [Time Frame: week 52] [Designated as safety issue: Yes]

Estimated Enrollment: 1200
Study Start Date: April 2008
Estimated Study Completion Date: September 2011
Estimated Primary Completion Date: July 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Arm 3: Experimental	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.
Arm 1: Experimental	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.
Arm 2: Experimental	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.
Arm 4: Active Comparator	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.

Eligibility

Ages Eligible for Study: 50 Years and older
Genders Eligible for Study: Both
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 and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00637377

Contacts

Contact: Bayer Clinical Trials Contact clinical-trials-contact@bayerhealthcare.com

Show 212 Study Locations

Sponsors and Collaborators

Bayer

Investigators

Study Director: Bayer Study Director Bayer

More Information

Additional Information:

Click here and search for drug information provided by the FDA

Click here and search for information on any recalls, market or product safety alerts by the FDA which might have occurred with this product

Click here to find results for studies related to marketed products

No publications provided

Responsible Party: Bayer Schering Pharma AG (Therapeutic Area Head)
Study ID Numbers: 91689, EurdaCT No.: 2007-000583-25
Study First Received: March 12, 2008
Last Updated: July 3, 2009
ClinicalTrials.gov Identifier: NCT00637377 History of Changes
Health Authority: Switzerland: Ethikkommission

Keywords provided by Bayer:
Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study placed in the following topic categories:
Eye Diseases
Mitogens
Retinal Degeneration
Macular Degeneration
Blindness
Endothelial Growth Factors
Retinal Diseases
Vision, Low

Additional relevant MeSH terms:
Growth Substances
Eye Diseases
Physiological Effects of Drugs
Retinal Degeneration
Macular Degeneration
Endothelial Growth Factors
Pharmacologic Actions
Retinal Diseases

ClinicalTrials.gov processed this record on August 12, 2009

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Links to all studies - primarily for crawlers

https://web.archive.org/web/20090911163626/https://clinicaltrials.gov/ct2/show/NCT00509795

INTERNET ARCHIVE WayBackMachine https://clinicaltrials.gov/ct2/show/NCT00509795 Go MAY SEP FEB 11 2008 2009 2011 21 captures 1 Dec 2008 – 23 Sep 2020 About this capture

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration(AMD) (VIEW 1)

This study is currently recruiting participants.
Verified by Regeneron Pharmaceuticals, April 2009

First Received: July 31, 2007 Last Updated: April 28, 2009 History of Changes

Sponsors and Collaborators:	**Regeneron Pharmaceuticals** Bayer
Information provided by:	Regeneron Pharmaceuticals
ClinicalTrials.gov Identifier:	NCT00509795

Purpose

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.

Condition	Intervention	Phase
Macular Degeneration	Drug: VEGF Trap-Eye Drug: Ranibizumab	Phase III

Study Type: Interventional
Study Design: Treatment, Randomized, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Active Control, Parallel Assignment, Safety/Efficacy Study

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

Resource links provided by NLM:

Genetics Home Reference related topics: X-linked juvenile retinoschisis

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Ranibizumab Aflibercept

U.S. FDA Resources

Further study details as provided by Regeneron Pharmaceuticals:

Primary Outcome Measures:

- 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) [Time Frame: Week 52] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52 [Time Frame: Week 52] [Designated as safety issue: Yes]
- The proportion of subjects who gain at least 15 letters of vision at Week 52 [Time Frame: Week 52] [Designated as safety issue: No]
- Mean change from baseline in total NEI VFQ-25 score at Week 52 [Time Frame: Week 52] [Designated as safety issue: No]
- Mean change from baseline in CNV area at Week 52 [Time Frame: Week 52] [Designated as safety issue: Yes]

Estimated Enrollment: 1200
Study Start Date: August 2007
Estimated Study Completion Date: December 2011
Estimated Primary Completion Date: December 2011 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1: Experimental	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.
2: Experimental	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.
3: Experimental	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.
4: Active Comparator	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.

Eligibility

Ages Eligible for Study: 50 Years and older
Genders Eligible for Study: Both
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 and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00509795

Contacts

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

Show 191 Study Locations

Sponsors and Collaborators

Regeneron Pharmaceuticals

Bayer

Investigators

Study Director: Avner Ingerman, MD Regeneron Pharmaceuticals

More Information

No publications provided

Responsible Party: Regeneron Pharmaceuticals (Dr. Avner Ingerman)
Study ID Numbers: VGFT-OD-0605
Study First Received: July 31, 2007
Last Updated: April 28, 2009
ClinicalTrials.gov Identifier: NCT00509795 History of Changes
Health Authority: United States: Food and Drug Administration; Canada: Health Canada

Study placed in the following topic categories:

Eye Diseases
Mitogens
Retinal Degeneration
Macular Degeneration
Endothelial Growth Factors
Retinal Diseases

Additional relevant MeSH terms:

Growth Substances
Eye Diseases
Physiological Effects of Drugs
Retinal Degeneration
Macular Degeneration
Endothelial Growth Factors
Pharmacologic Actions
Retinal Diseases

ClinicalTrials.gov processed this record on September 11, 2009

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JURAT

State/Commonwealthof FLORIDA)
☐City ☑County of Broward)

On 01/27/2021 (Date), before me, Mikhail Clarke (Notary Name),
the foregoing instrument was subscribed and sworn (or affirmed) before me by:

Duncan Hall
Name of Affiant(s)

❑ Personally known to me **-- OR --**

❑ Proved to me on the basis of the oath of _____ (Name of Credible Witness) **-- OR --**

☑ Proved to me on the basis of satisfactory evidence: driver_license (Type of ID Presented)

MIKHAIL CLARKE
Notary Public - State of Florida
Commission # HH7610
Expires on June 8, 2024

Notarized online using audio-video communication

WITNESS my hand and official seal.

Notary Public Signature: _____

Notary Name: Mikhail Clarke

Notary Commission Number: HH7610

Notary Commission Expires: 06/08/2024

Notarized online using audio-video communication

DESCRIPTION OF ATTACHED DOCUMENT

Title or Type of Document: Affidavit of Authenticity

Document Date: 01/27/2021

Number of Pages (including notarial certificate): 11