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

ClinicalTrials.gov Identifier: NCT00320788

Recruitment Status : Completed
First Posted : May 3, 2006
Results First Posted : March 1, 2012
Last Update Posted : March 1, 2012

Sponsor:
Regeneron Pharmaceuticals

Collaborator:
Bayer

Information provided by (Responsible Party):
Regeneron Pharmaceuticals

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

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.

Condition or disease	Intervention/treatment	Phase
Macular Degeneration	Biological: aflibercept injection (VEGF Trap-Eye, BAY86-5321)	Phase 2

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.

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

159 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Triple (Participant, Care Provider, Investigator)

Primary Purpose:

Treatment

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

Study Start Date :

Actual Primary Completion Date :

June 2008

Actual Study Completion Date :

August 2008

Resource links provided by the National Library of Medicine

MedlinePlus Genetics related topics: Age-related macular degeneration

MedlinePlus related topics: Macular Degeneration

Drug Information available for: Aflibercept Ziv-aflibercept

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
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

Arm	Intervention/treatment
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

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Primary Outcome Measures :

1. Mean Change of CR/LT From Baseline at Week 12 [Time Frame: Baseline and at Week 12]

CR/LT measured in micrometers (µm); lower individual values represent better outcomes.

Secondary Outcome Measures :

1. Mean Percent Change of CR/LT From Baseline at Week 12 [Time Frame: Baseline and at Week 12]

   CR/LT measured in micrometers (µm); a more negative percentage represents a better outcome

2. Mean Change in Best Corrected Visual Acuity (BCVA) as Measured by Early Treatment Diabetic Retinopathy Study (ETDRS) From Baseline at Week 12 [Time Frame: Baseline and at week 12]

   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

3. Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score From Baseline at Week 12 [Time Frame: At Week 12]

   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

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

50 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

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