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Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00943072

Recruitment Status : Completed
First Posted : July 21, 2009
Results First Posted : May 27, 2013
Last Update Posted : May 27, 2013

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

Study Description

Go to

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IPR2021-00881
U.S. Pat. 9,254,338
Exhibit 2126

This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Condition or disease	Intervention/treatment	Phase
Macular Edema Secondary to Central Retinal Vein Occlusion	Biological: VEGF Trap-Eye 2.0mg Drug: Sham	Phase 3

Study Design

Go to

Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

189 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

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

Primary Purpose:

Treatment

Official Title:

A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With Macular Edema Secondary to Central Retinal Vein Occlusion

Study Start Date :

July 2009

Actual Primary Completion Date :

October 2010

Actual Study Completion Date :

April 2012

Resource links provided by the National Library of Medicine

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MedlinePlus related topics: Edema

Drug Information available for: Aflibercept Ziv-aflibercept

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Go to

Primary Outcome Measures :

1. Percentage of Participants Who Gained at Least 15 Letters in BCVA at Week 24 as Measured by ETDRS Letter Score [Time Frame: Baseline and at Week 24]

   Percentage values indicate the number of subjects in each arm who were able to read an additional 15 letters or more at Week 24 compared to baseline.

   Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 24 letters (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Secondary Outcome Measures :

1. Change From Baseline in BCVA as Measured by ETDRS Letter Score at Week 24 - Last Observation Carried Forward (LOCF) [Time Frame: Baseline and at Week 24]

   Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 24 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

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2. Change From Baseline in Central Retinal Thickness (CRT) at Week 24 - LOCF
   [Time Frame: Baseline and at Week 24]
3. Percentage of Participants Progressing to Any of the Following: Anterior Segment Neovascularization, New Vessels of the Disc (NVD) or New Vessels Elsewhere (NVE) During the First 24 Weeks [Time Frame: Baseline to Week 24]
4. Change From Baseline in the NEI VFQ-25 in Total Score at Week 24 (LOCF)
   [Time Frame: Baseline and at Week 24]

   The NEI VFQ-25 assesses visual function and quality of life. 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.

Eligibility Criteria

Go to

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:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Criteria

Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

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Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts and Locations

Go to

Information from the National Library of Medicine

NIH NLM

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT00943072***

Locations

▶ Show 61 study locations

Sponsors and Collaborators

Regeneron Pharmaceuticals

Bayer

Investigators

Study Director: Clinical Trial Management Regeneron Pharmaceuticals

More Information

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Responsible Party:

Regeneron Pharmaceuticals

ClinicalTrials.gov Identifier:

NCT00943072 History of Changes

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