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COMPLETED ⓘ

A Study of the Efficacy and Safety of Ranibizumab Injection in Patients With Macular Edema Secondary to Branch Retinal Vein Occlusion (BRAVO) (BRAVO)

ClinicalTrials.gov ID ⓘ NCT00486018

Sponsor ⓘ Genentech, Inc.

Information provided by ⓘ Genentech, Inc. (Responsible Party)

Last Update Posted ⓘ 2017-05-10

Record History Tab

Study Record Versions

- This table shows the list of all the versions of this study record arranged in order by date.
- The first column shows the date the study record was updated, and the second column shows the elements in the study record that were changed.
 - To view a version of a study record, click the version date.
 - To compare versions, select two versions using the check boxes and click the "Compare" button at the bottom of the list.

☐	2007-06-11	None (earliest version on record)
☐	2007-08-06	Recruitment Status Study Status

Compare



		Contacts/Locations Eligibility Outcome Measures
☐	2007-08-30	Study Status Contacts/Locations
☐	2007-11-19	Study Status Arms and Interventions Eligibility Study Description
☐	2008-09-24	Study Status Contacts/Locations Study Identification Conditions Study Design Arms and Interventions Outcome Measures Eligibility Sponsor/Collaborators
☐	2009-02-02	Recruitment Status Study Status
☐	2010-03-04	Recruitment Status Study Status
☐	2010-05-05	Study Status Study Design
☐	2011-02-01	Study Status Outcome Measures Study Description Arms and Interventions Eligibility

		Participant Flow Baseline Characteristics Adverse Events More Information Sponsor/Collaborators
☐	2011-04-25	Study Status Outcome Measures
☐	2016-11-25	Study Status Baseline Characteristics Sponsor/Collaborators
☐	2017-04-04	Study Status Baseline Characteristics
Date		Changes

Version 8: 2010-05-05

Study Details

Date

Changes

Unique Protocol ID

FVF4165g

Brief Title

A Study of the Efficacy and Safety of Ranibizumab Injection in Patients With Macular Edema Secondary to Branch Retinal Vein Occlusion (BRAVO)

Official Title

A Phase III, Multicenter, Randomized, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab Injection

Compared With Sham in Subjects With Macular Edema Secondary to Branch Retinal Vein Occlusion
Secondary IDs

Study Status

Record Verification
2010-05
Overall Status
Completed
Study Start
2007-07
Primary Completion
2009-05 [Actual]
Study Completion
2009-11 [Actual]
First Submitted
2007-06-11
First Submitted that Met QC Criteria

Date **Changes**

First Posted
2007-06-13
Last Update Submitted that Met QC Criteria
2010-05-05
Last Update Posted
2010-05-07 [Estimated]

Sponsor/Collaborator

Sponsor

Genentech, Inc.

Responsible Party

Collaborators

Oversight

U.S. FDA-regulated Drug

U.S. FDA-regulated Device

Data Monitoring

Study Description

Brief Summary

This study is a Phase III, multicenter, randomized, double-masked, sham injection-controlled study of the efficacy and safety of intravitreal ranibizumab compared with sham injections in subjects with macular edema secondary to branch retinal vein occlusion (BRVO). Approximately 390 subjects with BRVO will be randomized at approximately 100 investigational sites in the United States.

Detailed Description

Conditions

Condition
Macular Edema Retinal Vein Occlusion
Keywords
Lucentis RVO BRVO Edema

Study Design

Study Type
Interventional
Primary Purpose
Treatment
Study Phase
Phase 3
Interventional Study Model
Parallel Assignment
Interventional Model Description
Number of Arms
3
Masking
Double (Participant, Investigator)
Masking Description
Allocation

Randomized
Enrollment
397 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1	Drug: ranibizumab Intravitreal injection repeating dose
Experimental: 2	Drug: ranibizumab Intravitreal injection repeating dose
Sham Comparator: 3	Drug: sham Intravitreal sham injection repeating dose

Outcome Measures

Primary Outcome Measures
1. Mean change from baseline in BCVA score [Time Frame: 6 months]
Secondary Outcome Measures
1. Proportion of subjects who gain at least 15 letters in BCVA score at 6 months compared with baseline [Time Frame: 6 months]
2. Proportion of subjects who lose fewer than 15 letters in BCVA score at 6 months compared with baseline [Time Frame: 6 months]
3. Mean change from baseline in BCVA score [Time Frame: 6 months]

4. Proportion of subjects with a central foveal thickness of ≤ 250 μm , assessed by OCT
[Time Frame: 6 months]
5. Mean absolute change from baseline in central foveal thickness, assessed by OCT
[Time Frame: 6 months]
6. Mean change from baseline in the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) near activities subscale
[Time Frame: 6 months]
7. Mean change from baseline in the NEI VFQ-25 distance activities subscale
[Time Frame: 6 months]

Eligibility

Minimum Age
18 Years
Maximum Age
Sex
All
Accepts Healthy Volunteers
No
Criteria
Inclusion Criteria: • Willingness to provide signed Informed Consent Form • Age ≥ 18 years • For sexually active women of childbearing potential, use of an appropriate form of contraception (or abstinence) for the duration of the study • Ability and willingness to return for all scheduled visits and assessments • Foveal center-involved macular edema secondary to branch retinal vein occlusion (BRVO) Exclusion Criteria: • History of cerebral vascular accident or myocardial infarction within 3 months prior to Day 0

- History of any anti-VEGF treatment in fellow eye within 3 months prior to Day 0
- History of any systemic anti-VEGF or pro-VEGF treatment within 6 months prior to Day 0
- History of allergy to fluorescein
- History of allergy to ranibizumab injection or related molecule
- Relevant systemic disease that may be associated with increased systemic VEGF levels (namely, all active malignancies); history of successfully treated malignancies is not an exclusion criterion
- Uncontrolled blood pressure
- Pregnancy or lactation
- Any condition that, in the opinion of the investigator, would preclude participation in the study (e.g., chronic alcoholism or drug abuse, personality disorder or use of major tranquilizers, indicated difficulty in long-term follow-up, and likelihood of survival of less than 1 year)
- Participation in an investigational trial within 30 days prior to Day 0 that involved treatment with any drug (excluding vitamins and minerals) or device that has not received regulatory approval at time of study entry

Ocular Exclusion Criteria (Study Eye):

- Prior episode of retinal vein occlusion (RVO)
- Brisk afferent pupillary defect
- History of radial optic neurotomy or sheathotomy
- History or presence of AMD (dry or wet form)
- History of any anti-VEGF treatment in the study eye within 3 months prior to Day 0
- History of laser photocoagulation for macular edema within 4 months prior to Day 0
- History of panretinal scatter photocoagulation or sector laser photocoagulation within 3 months prior to randomization or anticipated within the next 4 months following randomization
- History of intraocular corticosteroid use within 3 months prior to Day 0
- History of pars plana vitrectomy
- History of intraocular surgery (including cataract extraction, scleral buckle, etc.) within 2 months prior to Day 0 or anticipated within the next 7 months following Day 0
- History of yttrium-aluminum-garnet capsulotomy performed within 2 months prior to Day 0
- Previous filtration surgery in the study eye
- History of herpetic ocular infection
- History of ocular toxoplasmosis
- History of rhegmatogenous retinal detachment
- History of idiopathic central serous chorioretinopathy
- Evidence upon examination of vitreoretinal interface disease (e.g., vitreomacular traction, epiretinal membrane), either on clinical examination or OCT, thought to be contributing to macular edema
- An eye that, in the investigator's opinion, would not benefit from resolution of macular edema, such as eyes with foveal atrophy, dense pigmentary changes, or dense subfoveal hard exudates

- Presence of an ocular condition that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the study (e.g., uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass syndrome, or prior macula-off rhegmatogenous retinal detachment)
- Visually significant hemorrhage obscuring the fovea and felt to be a major contributor to reduced visual acuity
- Presence of a substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by 3 lines or more (i.e., a 20/40 cataract)
- Aphakia
- Relevant ocular disease that may be associated with increased intraocular VEGF levels (namely, uveitis, neovascular glaucoma, neovascular AMD, diabetic retinopathy, diabetic maculopathy, or ocular ischemic syndrome)
- Improvement of > 10 letters on BCVA between screening and Day 0

Contacts/Locations

Central Contact Person

Study Officials

- Name
Roman Rubio, M.D.
- Role
Study Director
- Affiliation
Genentech, Inc.

Location

IPD Sharing

Available IPD/Information
IPD information

References

Citations
• Suner IJ, Bressler NM, Varma R, Lee P, Dolan CM, Ward J, Colman S, Rubio RG. Reading speed improvements in retinal vein occlusion after ranibizumab treatment. JAMA Ophthalmol. 2013 Jul;131(7):851-6. doi: 10.1001/jamaophthalmol.2013.114. • Bhisitkul RB, Campochiaro PA, Shapiro H, Rubio RG. Predictive value in retinal vein occlusions of early versus late or incomplete ranibizumab response defined by optical coherence tomography. Ophthalmology. 2013 May;120(5):1057-63. doi: 10.1016/j.ophtha.2012.11.011. Epub 2013 Feb 14.
Links

Document Section