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



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: NCT00486018

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : June 13, 2007

[Results First Posted](#) ⓘ : February 25, 2011

[Last Update Posted](#) ⓘ : May 10, 2017

Sponsor:

Genentech, Inc.

Information provided by (Responsible Party):

Genentech, Inc.

Mylan v. Regeneron
IPR2021-00881
U.S. Pat. 9,254,338
Exhibit 2124

[Study Details](#)

[Tabular View](#)

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Study Description

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Brief Summary:

This was a Phase III, multicenter, randomized, double-masked, sham injection-controlled study of the efficacy and safety of intravitreal ranibizumab compared with sham injections in patients with macular edema secondary to branch

retinal vein occlusion (BRVO); 397 patients with BRVO were enrolled at 93 investigational sites in the United States. The study included a treatment period (6 months) and an observation period (6 months).

Condition or disease ⓘ	Intervention/treatment ⓘ	Phase ⓘ
Macular Edema	Drug: Ranibizumab injection 0.3 mg	Phase 3
Retinal Vein Occlusion	Drug: Ranibizumab injection 0.5 mg	
	Drug: Sham injection	

Study Design

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Study Type ⓘ :

Interventional (Clinical Trial)

Actual Enrollment ⓘ :

397 participants

Allocation:

Randomized

Intervention Model:

Parallel Assignment

Masking:

Double (Participant, Investigator)

Primary Purpose:

Treatment

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

Study Start Date ⓘ :

July 2007

Actual Primary Completion Date ⓘ :

May 2009

Actual Study Completion Date ⓘ :

November 2009

Resource links provided by the National Library of Medicine





[Drug Information](#) available for: [Ranibizumab](#)

[U.S. FDA Resources](#)

Arms and Interventions

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Arm 	Intervention/treatment 
Sham Comparator: Sham injection	Drug: Sham injection Sham injection in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six sham injections.
Experimental: Ranibizumab injection 0.3 mg	Drug: Ranibizumab injection 0.3 mg Ranibizumab injection 0.3 mg in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six injections. Other Name: Lucentis
Experimental: Ranibizumab injection 0.5 mg	Drug: Ranibizumab injection 0.5 mg Ranibizumab injection 0.5 mg in a single-dose regimen given every month (Day 0 through the Month 5 visit), for a total of six injections. Other Name: Lucentis

Outcome Measures

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Primary Outcome Measures :

1. Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) Score at 6 Months
[Time Frame: Baseline and 6 months]

BCVA score in the study eye was based on the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters.

1. Percentage of Participants Who Gained ≥ 15 Letters in BCVA Score at Month 6 Compared With Baseline [Time Frame: Baseline and 6 months]

BCVA score based on the ETDRS visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters.

2. Percentage of Participants Who Lost < 15 Letters in BCVA Score at Month 6 Compared With Baseline [Time Frame: Baseline and 6 months]

BCVA score based on the ETDRS visual acuity charts (number of correct letters) and assessed at a starting distance of 4 meters. The percentage of subjects who lost < 15 letters will be greater than the percentage of subjects who "gained ≥ 15 letters" as "losing < 15 letters" includes both those who gained ≥ 15 letters and those who were "stable" (i.e. lost between 1 and 14 letters, had no change, or gained between 1 and 14 letters).

3. Percentage of Participants With a Central Foveal Thickness of $\leq 250 \mu\text{m}$ at Month 6 [Time Frame: 6 months]

A central reading center assessed all optical coherence tomography (OCT) images. Central foveal thickness was defined as the center point thickness.

4. Mean Absolute Change From Baseline in Central Foveal Thickness at Month 6 [Time Frame: Baseline and 6 months]

A central reading center assessed all OCT images. Central foveal thickness was defined as the center point thickness.

5. Mean Change From Baseline in the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) Near Activities Subscale Score at Month 6 [Time Frame: Baseline and 6 months]

The NEI VFQ-25 (v. 2000; Interviewer Format) consisted of the base set of 25 questions, plus the optional additional questions (where questions A3, A4, and A5 pertained to the Near Activities Subscale). Scores ranged from 0 to 100; a higher score represented better functioning.

6. Mean Change From Baseline in the NEI VFQ-25 Distance Activities Subscale Score at Month 6 [Time Frame: Baseline and 6 months]

The NEI VFQ-25 (v. 2000; Interviewer Format) consisted of the base set of 25 questions, plus the optional additional questions (where questions A6, A7, and A8 pertained to the Distance Activities Subscale). Scores ranged from 0 to 100; a higher score represented better functioning.

Eligibility CriteriaGo 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:**

- 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

Ocular Inclusion Criterion (Study Eye):

- Foveal center-involved macular edema secondary to BRVO
- BCVA using ETDRS charts of 20/40 to 20/400 (Snellen equivalent)
- Mean central subfield thickness ≥ 250 μm on two optical coherence tomography (OCT) measurements (at screening [confirmed by the central reading center] and Day 0 [confirmed by the evaluating physician])
- Media clarity, pupillary dilation, and participant cooperation sufficient to obtain adequate fundus photographs

Exclusion Criteria:

- History of cerebral vascular accident or myocardial infarction within 3 months prior to Day 0
- History of any anti-vascular endothelial growth factor (VEGF) treatment in fellow eye within 3 months prior

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