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## A Study of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema (ME) With Center Involvement Secondary to Diabetes Mellitus (RIDE) (RIDE)



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: NCT00473382

[Recruitment Status](#) ⓘ : Completed

[First Posted](#) ⓘ : May 15, 2007

[Results First Posted](#) ⓘ : January 17, 2013

[Last Update Posted](#) ⓘ : April 17, 2017

**Sponsor:**

Genentech, Inc.

Mylan v. Regeneron  
IPR2021-00881  
U.S. Pat. 9,254,338  
Exhibit 2123

Genentech, Inc.

[Study Details](#)[Tabular View](#)[Study Results](#)[Disclaimer](#)[How to Read a Study Record](#)

## Study Description

Go to 

### Brief Summary:

This study is a Phase III, double-masked, multicenter, randomized, sham injection-controlled study of the efficacy and safety of ranibizumab injection in patients with clinically significant macular edema with center involvement (CSME-CI) secondary to diabetes mellitus (Type 1 or 2). This study is identical in design to study NCT00473330 (Protocol ID FVF4170g).

The open-label extension phase of the study was stopped after receiving FDA approval of the study drug (ranibizumab) for diabetic macular edema.

| <a href="#">Condition or disease</a> ⓘ | <a href="#">Intervention/treatment</a> ⓘ | <a href="#">Phase</a> ⓘ |
|--|--|-------------------------|
| Diabetes Mellitus                      | Drug: Ranibizumab                        | Phase 3                 |
| Macular Edema                          | Drug: Sham injection                     |                         |

### Detailed Description:

This study is composed of 3 phases: (1) A 24-month controlled treatment period (monthly treatment with ranibizumab 0.3 mg, ranibizumab 0.5 mg, or sham injection) followed by (2) a 12-month treatment period in which patients randomized to the sham group who had not discontinued from treatment (still masked) could choose to receive monthly ranibizumab 0.5 mg while the 2 ranibizumab treatment groups continued on the same treatment they received in the first 2 years. Patients who had not discontinued treatment by Month 36 were eligible to continue treatment with ranibizumab 0.5 mg as needed (pro re nata, PRN) in (3) an extension phase of the study for up to 2 more years, resulting in up to 5 years possible total treatment time for some patients.

As per the protocol, Genentech terminated the study approximately 30 days after approval of ranibizumab for diabetic macular edema in the United States.

## Study Design

Go to 

### [Study Type](#) ⓘ :

Interventional (Clinical Trial)

### [Actual Enrollment](#) ⓘ :

382 participants

**Allocation:**

Randomized

**Intervention Model:**

Parallel Assignment

**Masking:**

Double (Participant, Investigator)

**Primary Purpose:**

Treatment

**Official Title:**

A Phase III, Double-masked, Multicenter, Randomized, Sham Injection-controlled Study of the Efficacy and Safety of Ranibizumab Injection in Subjects With Clinically Significant Macular Edema With Center Involvement Secondary to Diabetes Mellitus

**Study Start Date** ⓘ :

June 2007

**Actual Primary Completion Date** ⓘ :



January 2011

**Actual Study Completion Date** ⓘ :

September 2012

**Resource links provided by the National Library of Medicine**[MedlinePlus](#) related topics: [Edema](#)[Drug Information](#) available for: [Ranibizumab](#)[U.S. FDA Resources](#)**Arms and Interventions**Go to 

| <a href="#">Arm</a> ⓘ | <a href="#">Intervention/treatment</a> ⓘ |
|-----------------------|--|
|-----------------------|--|

| Arm   | Intervention/treatment  |
|---|---|
| <p>Experimental: Ranibizumab 0.3 mg</p> <p>Patients received ranibizumab 0.3 mg monthly administered intravitreally for 36 months. Patients who had not discontinued treatment by Month 36 could enter the open-label extension phase to receive ranibizumab 0.5 mg as needed (pro re nata [PRN]) for up to 24 additional months.</p>   | <p>Drug: Ranibizumab</p> <p>Sterile solution for intravitreal injection.</p> <p>Other Name: Lucentis</p>  |
| <p>Experimental: Ranibizumab 0.5 mg</p> <p>Patients received ranibizumab 0.5 mg monthly administered intravitreally for 36 months. Patients who had not discontinued treatment by Month 36 could enter the open-label extension phase to receive ranibizumab 0.5 mg as needed (pro re nata [PRN]) for up to 24 additional months.</p>   | <p>Drug: Ranibizumab</p> <p>Sterile solution for intravitreal injection.</p> <p>Other Name: Lucentis</p>  |
| <p>Sham Comparator: Sham injection/ranibizumab 0.5 mg</p> <p>Patients received a sham intravitreal injection monthly for 24 months. Patients who had not discontinued treatment by Month 24 could choose to receive ranibizumab 0.5 mg monthly administered intravitreally for the subsequent 12 months. Patients who had not discontinued treatment by Month 36 could enter the open-label extension phase to receive ranibizumab 0.5 mg as needed (pro re nata [PRN]) for up to 24 additional months.</p> | <p>Drug: Sham injection</p>   |

## Outcome Measures

Go to 

### Primary Outcome Measures :

1. Percentage of Patients Who Gained  $\geq 15$  Letters in Their Best Corrected Visual Acuity (BCVA) Score From Baseline at Month 24 [ Time Frame: Baseline to Month 24 ]

BCVA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity (VA) chart starting at a test distance of 4 meters. The BCVA score is the number of letters read

### Secondary Outcome Measures ⓘ :

1. Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) Score at Months 24, 36, and 48 [ Time Frame: Baseline to Month 48 ]

BCVA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity (VA) chart starting at a test distance of 4 meters. The BCVA score is the number of letters read correctly by the patient. An increase in the BCVA score indicates an improvement of vision. A positive change score indicates improvement.

2. Percentage of Patients With a Visual Acuity (VA) Snellen Equivalent of 20/40 or Better at Months 24, 36, and 48 [ Time Frame: Months 24, 36, and 48 ]

VA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity chart starting at a test distance of 4 meters. An increase in the number of lines read correctly by the patient in the ETDRS chart indicates an improvement of vision. The Snellen equivalent of 20/40 or better is 69 or more letters correctly read in the EDTRS chart.

3. Percentage of Patients Who Lost < 15 Letters in Their Best Corrected Visual Acuity (BCVA) Score From Baseline at Months 24, 36, and 48 [ Time Frame: Baseline to Month 48 ]

BCVA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity (VA) chart starting at a test distance of 4 meters. The BCVA score is the number of letters read correctly by the patient. An increase in the BCVA score indicates an improvement of vision.

4. Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) Score at Months 24 and 36 in Patients With Focal Edema at Baseline [ Time Frame: Baseline to Month 36 ]

BCVA was measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) visual acuity (VA) chart starting at a test distance of 4 meters. The BCVA score is the number of letters read correctly by the patient. An increase in the BCVA score indicates an improvement of vision. A positive change score indicates improvement.

5. Mean Change From Baseline in Central Foveal Thickness at Months 24, 36, and 48 [ Time Frame: Baseline to Month 48 ]

Central foveal thickness was assessed in optical coherence tomographic images by the central reading center. A decrease in foveal thickness suggests a reduction in macular edema. A negative change score indicates improvement.

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