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COMPLETED 

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

ClinicalTrials.gov ID  NCT00473330

Sponsor  Genentech, Inc.

Information provided by  Genentech, Inc. (Responsible Party)

Last Update Posted  2017-04-17

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.

☐	2007-05-13	None (earliest version on record)
☐	2007-07-12	Recruitment Status

Compare

Feedback 

		Study Status Contacts/Locations
☐	2007-08-06	Study Status Contacts/Locations
☐	2007-09-12	Study Status Contacts/Locations
☐	2007-10-15	Study Status Conditions Arms and Interventions Outcome Measures Eligibility Contacts/Locations Study Identification Study Description
☐	2008-09-24	Study Status Contacts/Locations Study Identification Conditions Study Design Arms and Interventions Sponsor/Collaborators Outcome Measures Eligibility
☐	2009-02-02	Recruitment Status Study Status
☐	2009-11-02	Study Status Contacts/Locations Outcome Measures
☐	2010-11-11	Study Status

☐	2012-12-10	Study Status Study Identification Sponsor/Collaborators Study Description Conditions Study Design Arms and Interventions Outcome Measures Eligibility Participant Flow Baseline Characteristics Adverse Events More Information
☐	2013-07-31	Recruitment Status Study Status
☐	2014-08-25	Study Status Study Description Arms and Interventions Outcome Measures Participant Flow Baseline Characteristics Adverse Events More Information
	Date	Changes

Version 9: 2010-11-11

Date**Changes**

Study Details

Study Identification

Unique Protocol ID

FVF4170g

Brief Title

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

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

Secondary IDs

Study Status

Record Verification

2010-11

Overall Status

Active, not recruiting

Study Start

2007-07

Primary Completion

2012-10 [Estimated]

Study Completion

Date

Changes

2007-05-13

First Submitted that Met QC Criteria

2007-05-13

First Posted

2007-05-15

Last Update Submitted that Met QC Criteria

2010-11-11

Last Update Posted

2010-11-15 [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, double-masked, multicenter, randomized, sham injection-controlled study of the efficacy and safety of ranibizumab injection in patients with CSME-CI secondary to diabetes mellitus (Type 1 or 2).

Detailed Description**Conditions****Condition**

Diabetes Mellitus
Macular Edema

Keywords

Lucentis
DME
Diabetes
Vision Loss

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
366 [Estimated]

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 inje repeating dose

Outcome Measures

Primary Outcome Measures

1. The primary efficacy outcome measure is the proportion of subjects who gain at least 15 letters in BCVA compared with baseline
[Time Frame: 24 months]

Secondary Outcome Measures

1. Mean change from baseline in BCVA score over time
[Time Frame: 24 months]
2. Mean change from baseline in central foveal thickness (CFT) over time, as assessed on OCT by the central reading center
[Time Frame: 24 months]
3. Proportion of subjects with resolution of leakage at 24 months, as assessed by the central reading center using fluorescein angiography (FA)
[Time Frame: 24 months]
4. Mean number of macular laser treatments during 24 months
[Time Frame: 24 months]
5. Mean change from baseline in the National Eye Institute Visual Functioning Questionnaire-25 (NEI VFQ-25) near activities subscale score at 24 months
[Time Frame: 24 months]
6. Mean change from baseline in the NEI VFQ-25 distance activities subscale score at 24 months
[Time Frame: 24 months]
7. Proportion of subjects with a three-step change from baseline in the Early Treatment Diabetic Retinopathy Study (ETDRS) scale at 24 months, as assessed by the central reading center using fundus photography
[Time Frame: 24 months]
8. Mean change from baseline in contrast sensitivity at 24 months, measured by the number of letters read correctly on the Pelli-Robson chart
[Time Frame: 24 months]
9. Proportion of subjects who gain at least 15 letters in BCVA score compared with baseline at 36 months
[Time Frame: 36 months]
10. Mean change from baseline in BCVA score over time up to 36 months
[Time Frame: 36 months]
11. Mean change from baseline in central foveal thickness (CFT) over time up to 36 months, as assessed on OCT by the central reading center
[Time Frame: 36 months]
12. Mean number of macular laser treatments during 36 months
[Time Frame: 36 months]

13. Proportion of subjects with a three-step or greater progression from baseline in the ETDRS diabetic retinopathy severity level at 36 months, as assessed by the central reading center using FP

[Time Frame: 36 months]

14. Mean change from baseline in contrast sensitivity at 36 months, as measured by the number of letters read correctly on the Pelli-Robson chart

[Time Frame: 36 months]

Eligibility

Minimum Age

18 Years

Maximum Age

Sex

All

Accepts Healthy Volunteers

No

Criteria

Inclusion Criteria:

- Willingness to provide written informed consent and, at U.S. sites, Health Insurance Portability and Accountability Act (HIPAA) authorization and in other countries, as applicable according to national laws
- Age $\geq$ 18 years
- Diabetes mellitus (Type 1 or 2)
- Retinal thickening secondary to diabetes mellitus (DME) involving the center of the fovea
- Decrease in vision determined to be primarily the result of DME and not to other causes
- For sexually active women of childbearing potential, use of an appropriate form of contraception (or abstinence) for the duration of the study
- Ability (in the opinion of the investigator) and willingness to return for all scheduled visits and assessments

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye

- Panretinal photocoagulation (PRP) or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular corticosteroids in the study eye (e.g., TA) within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.) within 3 months of the Day 0 visit
- PDR in the study eye, with the exception of inactive, regressed PDR
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in the study eye
- Concurrent Ocular Conditions
- Vitreomacular traction or epiretinal membrane in the study eye
- Ocular inflammation (including trace or above) in the study eye
- History of idiopathic or autoimmune uveitis in either eye
- Structural damage to the center of the macula in the study eye that is likely to preclude improvement in VA following the resolution of macular edema, including atrophy of the RPE, subretinal fibrosis, or organized hard-exudate plaque
- Ocular disorders in the study eye that may confound interpretation of study results, including retinal vascular occlusion, retinal detachment, macular hole, or CNV of any cause (e.g., AMD, ocular histoplasmosis, or pathologic myopia)
- Concurrent disease in the study eye that would compromise VA or require medical or surgical intervention during the study period
- Cataract surgery in the study eye within 3 months, yttrium-aluminum-garnet (YAG) laser capsulotomy within the past 2 months, or any other intraocular surgery within the 90 days preceding Day 0
- Aphakia or absence of the posterior capsule in the study eye
- Uncontrolled glaucoma or previous filtration surgery in the study eye
- Spherical equivalent of the refractive error in the study eye of more than - 8 diopters myopia
- Evidence at examination of infectious blepharitis, keratitis, scleritis, or conjunctivitis in either eye or current treatment for serious systemic infection
- Uncontrolled blood pressure
- History of cerebral vascular accident or myocardial infarction within 3 months prior to Day 0
- Uncontrolled diabetes mellitus
- Renal failure requiring dialysis or renal transplant
- Participation in an investigational trial within 30 days prior to screening that involved treatment with any drug (excluding vitamins and minerals) or device
- History of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use an investigational drug, might affect interpretation of the results of the study, or renders the subject at high risk from treatment complications
- Pregnancy or lactation
- History of allergy to fluorescein

- History of allergy to ranibizumab injection or related molecule

Contacts/Locations

Central Contact Person

Study Officials

- Name
Jason Ehrlich, M.D., Ph.D.
Role
Study Director
Affiliation
Genentech, Inc.

Location

IPD Sharing

Available IPD/Information

IPD information

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Citations

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Links

Document Section