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

This study is ongoing, but not recruiting participants.

First Received: May 13, 2007 Last Updated: November 2, 2009 History of Changes

Sponsor:	Genentech
Information provided by:	Genentech
ClinicalTrials.gov Identifier:	NCT00473330

Purpose

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).

Condition	Intervention	Phase
Diabetes Mellitus Macular Edema	Drug: ranibizumab Drug: sham	Phase III

Study Type: Interventional
Study Design: Allocation: Randomized
Control: Placebo Control
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, 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

Resource links provided by NLM:

Genetics Home Reference related topics: X-linked juvenile retinoschisis

MedlinePlus related topics: Diabetes Edema

Drug Information available for: Ranibizumab

U.S. FDA Resources

Further study details as provided by Genentech:

Primary Outcome Measures:

- 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] [Designated as safety issue: No]

Secondary Outcome Measures:

- Mean change from baseline in BCVA score over time [Time Frame: 24 months] [Designated as safety issue: No]
- Mean change from baseline in central foveal thickness (CFT) over time, as assessed on OCT by the central reading center [Time Frame: 24 months] [Designated as safety issue: No]

- 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] [Designated as safety issue: No]
- Mean number of macular laser treatments during 24 months [Time Frame: 24 months] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]
- Mean change from baseline in the NEI VFQ-25 distance activities subscale score at 24 months [Time Frame: 24 months] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]
- Proportion of subjects who gain at least 15 letters in BCVA score compared with baseline at 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- Mean change from baseline in BCVA score over time up to 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]
- Mean number of macular laser treatments during 36 months [Time Frame: 36 months] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]
- 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] [Designated as safety issue: No]

Estimated Enrollment:	366
Study Start Date:	July 2007
Estimated Primary Completion Date:	October 2012 (Final data collection date for primary outcome measure)

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

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
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 ≥ 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:

- 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 and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00473330

Sponsors and Collaborators

Genentech

Investigators

Study Director: Jason Ehrlich, M.D., Ph.D. Genentech

More Information

No publications provided

Responsible Party:	Genentech, Inc. (Clinical Trials Posting Group)
ClinicalTrials.gov Identifier:	NCT00473330 History of Changes
Other Study ID Numbers:	FVF4170g
Study First Received:	May 13, 2007
Last Updated:	November 2, 2009
Health Authority:	United States: Food and Drug Administration

Keywords provided by Genentech:

Lucentis
DME
Diabetes
Vision Loss

Additional relevant MeSH terms:

Metabolic Diseases
Immunologic Factors
Eye Diseases
Physiological Effects of Drugs
Diabetes Mellitus
Edema
Endocrine System Diseases
Macular Degeneration
Retinal Degeneration
Pharmacologic Actions
Antibodies, Monoclonal
Macular Edema
Signs and Symptoms
Glucose Metabolism Disorders
Retinal Diseases

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