History of Changes for Study: NCT00090623

A Study of rhuFab V2 (Ranibizumab) in Subjects With Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration (AMD)

Latest version (submitted June 19, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	June 23, 2005	None (earliest Version on record)
2	○	○	September 5, 2006	Recruitment Status and Study Status
3	○	○	January 30, 2007	Study Status
4	○	○	September 1, 2009	Study Status and References
5	○	○	June 19, 2013	Study Status and Sponsor/Collaborators

Compare Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00090623
Submitted Date: June 23, 2005 (v1)

Study Identification

Unique Protocol ID: FVF3192g
Brief Title: A Study of rhuFab V2 (Ranibizumab) in Subjects With Subfoveal Choroidal Neovascularization Secondary to Age-Related Macular Degeneration (AMD)
Official Title: A Phase IIIb, Multicenter, Randomized, Double Masked, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab in Subjects With Subfoveal Choroidal Neovascularization (CNV) With or Without Classic CNV Secondary to Age Related Macular Degeneration
Secondary IDs:

Study Status

Record Verification: March 2005
Overall Status: Active, not recruiting
Study Start: August 2004
Primary Completion:
Study Completion:
First Submitted: August 30, 2004
First Submitted that Met QC Criteria: August 31, 2004
First Posted: September 1, 2004 [Estimate]
Last Update Submitted that Met QC Criteria: June 23, 2005
Last Update Posted: June 24, 2005 [Estimate]

Sponsor/Collaborators

Sponsor: Genentech, Inc.
Responsible Party:
Collaborators:

Oversight

U.S. FDA-regulated Drug:
U.S. FDA-regulated Device:
Data Monitoring:

Study Description

Brief Summary: This is a phase III, multicenter, randomized, double masked, sham injection-controlled study of the efficacy and safety of intravitreally administered ranibizumab in subjects with subfoveal choroidal neovascularization secondary to age-related macular degeneration.
Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Subfoveal neovascular
Age-related macular degeneration
AMD
Wet AMD

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model:

Number of Arms:

Masking: Double (masked roles unspecified)

Allocation: Randomized

Enrollment: 180

Arms and Interventions

Intervention Details:

Drug: rhuFab V2 (ranibizumab)

Outcome Measures

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent
- Age >=50 years
- Active primary or recurrent subfoveal CNV lesions secondary to AMD in the study eye
- Total area of CNV (including both classic and occult components) encompassed within the lesion >= 50% of the total lesion area
- Total lesion area <=12 disc areas in size
- Best corrected visual acuity (BCVA), using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts, of 20/40 to 20/320 (Snellen equivalent) in the study eye

Exclusion Criteria:

- Prior treatment with verteporfin, external-beam radiation therapy, or transpupillary thermotherapy in the study eye
- Treatment with verteporfin in the nonstudy eye <7 days preceding Day 0
- Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, anecortave acetate, protein kinase C inhibitors, etc.)
- Previous intravitreal drug delivery (e.g., intravitreal corticosteroid injection or device implantation) in the study eye
- Previous subfoveal focal laser photocoagulation in the study eye
- Laser photocoagulation (juxtafoveal or extrafoveal) in the study eye within 1 month preceding Day 0
- History of vitrectomy surgery in the study eye
- History of submacular surgery or other surgical intervention for AMD in the study eye
- Previous participation in any studies of investigational drugs within 1 month preceding Day 0 (excluding vitamins and minerals)
- Subretinal hemorrhage in the study eye that involves the center of the fovea, if the size of the hemorrhage is either >= 50% of the total lesion area or >=1 disc area in size
- Fibrosis or atrophy involving the center of the fovea in the study eye
- CNV in either eye due to other causes, such as ocular histoplasmosis, trauma, or pathologic myopia
- Retinal pigment epithelial tear involving the macula in the study eye
- Any concurrent intraocular condition in the study eye (e.g., cataract or diabetic retinopathy) that, in the opinion of the investigator, could either: (1) Require medical or surgical intervention during the 24-month study period to prevent or treat visual loss that might result from that condition, or (2) If allowed to progress untreated, could likely contribute to loss of at least 2 Snellen equivalent lines of BCVA over the 24-month study period
- Active intraocular inflammation (grade trace or above) in the study eye
- Current vitreous hemorrhage in the study eye
- History of rhegmatogenous retinal detachment or macular hole (Stage 3 or 4) in the study eye
- History of idiopathic or autoimmune-associated uveitis in either eye
- Infectious conjunctivitis, keratitis, scleritis, or endophthalmitis in either eye
- Aphakia or absence of the posterior capsule in the study eye
- Spherical equivalent of the refractive error in the study eye demonstrating more than -8 diopters of myopia
- Intraocular surgery (including cataract surgery) in the study eye within 2 months preceding Day 0
- Uncontrolled glaucoma in the study eye (defined as intraocular pressure >=30 mmHg despite treatment with antiglaucoma medication)
- History of glaucoma filtering surgery in the study eye
- History of corneal transplant in the study eye
- Premenopausal women not using adequate contraception
- 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 of an investigational drug or that might affect interpretation of the results of the study or render the subject at high risk for treatment complications
- Current treatment for active systemic infection
- History of allergy to fluorescein, not amenable to treatment
- Inability to obtain fundus photographs or fluorescein angiograms of sufficient quality to be analyzed and graded by the central reading center
- Inability to comply with study or follow up procedures

Contacts/Locations

Locations: **United States, Colorado**

Trial Information Support Line
Denver, Colorado, United States

IPDSharing

Plan to Share IPD:

References

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

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