History of Changes for Study: NCT00685854

Pilot Study of Intravitreal Injection of Ranibizumab for Macular Telangiectasia With Neovascularization (MACTEL 2)

Latest version (submitted June 30, 2017) 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	◉	◉	May 24, 2008	None (earliest Version on record)
2	○	○	June 18, 2008	Study Status
3	○	○	June 24, 2008	Study Description, Study Status and Study Identification
4	○	○	July 16, 2008	References and Study Status
5	○	○	July 18, 2008	Study Status
6	○	○	March 18, 2009	Study Status
7	○	○	June 9, 2009	Study Status
8	○	○	August 24, 2009	Study Status
9	○	○	November 25, 2009	Study Design and Study Status
10	○	○	March 13, 2010	Study Status
11	○	○	June 16, 2010	Study Status
12	○	○	July 7, 2010	Study Status
13	○	○	August 20, 2010	Study Status
14	○	○	September 17, 2010	References and Study Status
15	○	○	December 10, 2010	Recruitment Status, Study Status, Contacts/Locations, Study Design and References
16	○	○	December 14, 2010	Study Description and Study Status
17	○	○	December 22, 2010	Study Status
18	○	○	March 30, 2011	Recruitment Status, Study Status and References
19	○	○	September 26, 2015	Study Status
20	○	○	January 19, 2017	Study Status
21	○	○	January 20, 2017	Study Status
22	○	○	January 24, 2017	Study Status
23	○	○	June 30, 2017	Study Status

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

Scroll up to access the controls

Study NCT00685854
Submitted Date: May 24, 2008 (v1)

Study Identification

Unique Protocol ID: 080147
Brief Title: Pilot Study of Intravitreal Injection of Ranibizumab for Macular Telangiectasia With Neovascularization (MACTEL 2)
Official Title: Pilot Study of Intravitreal Injection of Ranibizumab for Macular Telangiectasia Without Neovascularization (MACTEL 2)
Secondary IDs: 08-EI-0147

Study Status

Record Verification: April 2008
Overall Status: Recruiting
Study Start: May 2008
Primary Completion:
Study Completion:
First Submitted: May 24, 2008
First Submitted that Met QC Criteria: May 24, 2008

First Posted: May 28, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: May 24, 2008

Last Update Posted: May 28, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: National Eye Institute (NEI)

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring:

Study Description

Brief Summary: Retinal telangiectasis is a group of rare, idiopathic retinal vascular anomalies affecting the retinal capillaries in which irregular capillary dilation and incompetence occur in the macula. This is the group 2 in the Gass classification of idiopathic juxtafoveal telangiectasia in which fluorescein angiography showed leakage with capillary dilation. These patients typically are diagnosed in their fifth or sixth decade of life. Both sexes may be affected. Minimal exudation, superficial retinal crystalline deposits, and right-angle venules characterize this disorder. The pathogenesis of the disease is unknown. Because of the leakage of the retinal vessels and also the finding of neovascularization, it is possible that vascular endothelial growth factor (VEGF) may be implicated in this disease.

The purpose of this study is to evaluate the possible role of ranibizumab for the treatment of eight participants with macular telangiectasia with hyperfluorescence on fluorescein angiography, with vision better than 20/400, without neovascularization. The primary outcome of this study will be the proportion of participants that lose 15 letters or more in ETDRS BCVA at 12 months compared with baseline. The secondary outcomes measured at one year will include the proportion of participants who lose 10 letters or more, the mean change in ETDRS BCVA, the change in central retinal thickness, the extent of fluorescein leakage, the change in fundus autofluorescence, change in size of neovascular membrane and the change in central retinal sensitivity. This is a pilot study designed to evaluate the feasibility and potential efficacy of treating patients with macular telangiectasia in a larger, phase III study within the organization of the MAC TEL Research Group, sponsored by the Lowy Foundation. Currently, the research group is enrolling 200 patients affected with this condition for a natural history study in 22 international clinical centers.

Detailed Description: Retinal telangiectasis is a group of rare, idiopathic retinal vascular anomalies affecting the retinal capillaries in which irregular capillary dilation and incompetence occur in the macula. This is the group 2 in the Gass classification of idiopathic juxtafoveal telangiectasia in which fluorescein angiography showed leakage with capillary dilation. These patients typically are diagnosed in their fifth or sixth decade of life. Both sexes may be affected. Minimal exudation, superficial retinal crystalline deposits, and right-angle venules characterize this disorder. The pathogenesis of the disease is unknown. Because of the leakage of the retinal vessels and also the finding of neovascularization, it is possible that vascular endothelial growth factor (VEGF) may be implicated in this disease.

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Conditions

Conditions: Macular Telangiectasia

Keywords: Macular Telangiectasia
Vascular Endothelial Growth Factor
Ranibizumab

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1

Interventional Study Model: Single Group Assignment

Number of Arms:

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 8

Arms and Interventions

Intervention Details:

Drug: Ranibizumab

Outcome Measures

Primary Outcome Measures:

1. Effect of intravitreal ranibizumab treatment on visual acuity

Secondary Outcome Measures:

1. ETDRS BCVA, area of retinal leakage, retinal thickness, area of hypofluoresence, central retinal sensitivity

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria:

- INCLUSION CRITERIA:
- Participant must understand and sign the informed consent.
- Participant must be at least 18 years of age.
- Participant must have macular telangiectasia in both eyes.
- Participant must have vision loss of better than 20/400 in the study eye.
- Participant must have clear ocular media and adequate pupillary dilation to permit good quality stereoscopic fundus photography.

- All women of childbearing potential must have a negative urine pregnancy test at baseline, and be willing to undergo testing immediately prior to each injection and monthly for at least two months following the last dose of ranibizumab.

EXCLUSION CRITERIA:

- Safety and toxicity of ranibizumab have not yet been investigated in children. Further, it is unlikely that younger participants will be able to comply with all examinations and intravitreal injections. Therefore, participants below the age of 18 will be excluded from participation in the study. This ocular condition is not commonly found in participants below the age of 18.
- Participant has neovascularization in either eye.
- History (within past five years) or evidence of severe cardiac disease (apparent in electrocardiogram abnormalities, clinical history of unstable angina, acute coronary syndrome, myocardial infarction, revascularization procedure within six months prior to baseline, atrial or ventricular tachyarrythmias requiring ongoing treatment).
- History of stroke within 12 months of study entry.
- History within the past 30 days of a chronic ocular or periocular infection (including any history of ocular herpes zoster).
- Current acute ocular or periocular infection.
- Any major surgical procedure within one month of study entry.
- Known serious allergies to fluorescein dye.
- Previous participation in a clinical trial (for either eye) involving anti-angiogenic drugs (pegaptanib, ranibizumab, bevacizumab, anecortave acetate, Protein Kinase C inhibitors, etc.).
- Previous intravitreal drug delivery (e.g., intravitreal corticosteroid injection or device implantation) in the study eye.
- History of vitrectomy surgery in the study eye.
- History of glaucoma filtering surgery in the study eye.
- History of corneal transplant in the study eye.
- Pregnancy (positive pregnancy test) or lactation and premenopausal women not using adequate contraception. The following are considered effective means of contraception: surgical sterilization or use of oral contraceptives, barrier contraception with either a condom or diaphragm in conjunction with spermicidal gel, an IUD, or contraceptive hormone implant or patch.

Contacts/Locations

Central Contact Person: Patient Recruitment and Public Liaison Office
Telephone: (800) 411-1222
Email: prpl@mail.cc.nih.gov

Central Contact Backup: TTY
Telephone: 1-866-411-1010

Locations: **United States, Maryland**

National Institutes of Health Clinical Center, 9000 Rockville Pike
[Recruiting]
Bethesda, Maryland, United States, 20892

IPDSharing

Plan to Share IPD:

References

Citations: Amin R, Puklin JE, Frank RN. Growth factor localization in choroidal neovascular membranes of age-related macular degeneration. Invest Ophthalmol Vis Sci. 1994 Jul;35(8):3178-88. PubMed 7519180

Links: URL: http://clinicalstudies.info.nih.gov/detail/A_2008-EI-0147.html
Description: NIH Clinical Center Detailed Web Page

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

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