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Macugen for Proliferative Diabetic Retinopathy Study With Extended Dosing (M-PDRS ED)

ClinicalTrials.gov Identifier: NCT01486771

Recruitment Status : Unknown
Verified December 2011 by Victor H. Gonzalez, MD, Valley Retina Institute.
Recruitment status was: Active, not recruiting
First Posted : December 6, 2011
Last Update Posted : December 6, 2011

Sponsor:
Valley Retina Institute

Collaborator:
Pfizer

Information provided by (Responsible Party):
Victor H. Gonzalez, MD, Valley Retina Institute

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

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Brief Summary:

Intravitreal injections of pegaptanib will induce the regression of Proliferative Diabetic Retinopathy (PDR) and reduce the need for retinal photocoagulation.

Condition or disease	Intervention/treatment	Phase
Proliferative Diabetic Retinopathy	Drug: Macugen ® (pegaptanib sodium)	Phase 4

Detailed Description:

Primary Objective:

To further establish the efficacy of intravitreal pegaptanib injections in the regression of retinal neovascularization secondary to high-risk PDR, as compared to standard panretinal photocoagulation (PRP)

Secondary Objective:

To maintain the regression of PDR after the induction phase with intravitreal pegaptanib injections administered at 12-week intervals, as compared to standard PRP

To maintain the regression of PDR after the induction phase with retinal photocoagulation applied to areas of ischemia (Selective Laser Photocoagulation), as compared to standard PRP

To evaluate the rate of recurrence of neovascularization after 6 intravitreal pegaptanib injections

To determine if intravitreal pegaptanib will reduce the area and/or volume of concomitant diabetic macular edema, as assessed by leakage on fluorescein angiography (FA) and/or optical coherence tomography (OCT)

To determine if intravitreal pegaptanib injections maintain or reduce the loss of best-corrected visual acuity

Study Design

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Study Type :

Interventional (Clinical Trial)

Actual Enrollment :

30 participants

Allocation:

Randomized

Intervention Model:

Factorial Assignment

Masking:

None (Open Label)

Primary Purpose:

Treatment

Official Title:

A Pilot Study to Determine if Intravitreal Injections of Pegaptanib Sodium (Macugen) Given Every 12 Weeks for a Year After an Induction Phase of Three Injections Every 6 Weeks Will Reduce the Progression of Proliferative Diabetic Retinopathy in Patients Without Significant Vitreous Hemorrhage in Comparison to Treatment With Retinal Photocoagulation Alone and After an Induction Phase

Study Start Date :

November 2007

Estimated Primary Completion Date :

August 2013

Estimated Study Completion Date :

February 2014

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Diabetic Eye Problems Retinal Disorders

Drug Information available for: Pegaptanib sodium

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment

Arm	Intervention/treatment
Experimental: IV Macugen Q6 Will receive 3 intravitreal pegaptanib injections at 6-week intervals, then 3 additional injections at 12-week intervals	Drug: Macugen ® (pegaptanib sodium) Patients assigned to either IV Mac Q6Arm will receive a total of 3 intravitreal pegaptanib sodium injections administered at 6-week intervals beginning on Day 0 and ending at Week 12. The group will then receive an intravitreal injection every 12 weeks. Patients assigned to IV Mac Q6Arm will receive a total of 3 intravitreal pegaptanib sodium injections administered at 6-week intervals beginning on Day 0 and ending at Week 12. After the third injection subjects in this group will receive Selective Laser Photocoagulation at Week 18. Patients assigned to Panretinal Photocoagulation will act as the control group. Subjects in this group will receive standard Panretinal Photocoagulation using a modified ETDRS protocol. All intravitreal study injections will consist of 0.3 milligrams (mg) of pegaptanib sodium delivered by intravitreal injection.

Arm	Intervention/treatment
Experimental: IV Mac Q6 Arm Will Selective Laser Photocoagulation after 3 intravitreal pegaptanib injections	Drug: Macugen ® (pegaptanib sodium) Patients assigned to either IV Mac Q6Arm will receive a total of 3 intravitreal pegaptanib sodium injections administered at 6-week intervals beginning on Day 0 and ending at Week 12. The group will then receive an intravitreal injection every 12 weeks. Patients assigned to IV Mac Q6Arm will receive a total of 3 intravitreal pegaptanib sodium injections administered at 6-week intervals beginning on Day 0 and ending at Week 12. After the third injection subjects in this group will receive Selective Laser Photocoagulation at Week 18. Patients assigned to Panretinal Photocoagulation will act as the control group. Subjects in this group will receive standard Panretinal Photocoagulation using a modified ETDRS protocol. All intravitreal study injections will consist of 0.3 milligrams (mg) of pegaptanib sodium delivered by intravitreal injection.

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