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COMPLETED ⓘ

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

ClinicalTrials.gov ID ⓘ NCT00943072

Sponsor ⓘ Regeneron Pharmaceuticals

Information provided by ⓘ Regeneron Pharmaceuticals (Responsible Party)

Last Update Posted ⓘ 2013-05-27

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.

☐	2009-07-20	None (earliest version on record)
☐	2009-09-03	Study Status Contacts/Locations
Compare		

Feedback

☐		
☐	2009-10-07	Study Status Contacts/Locations
☐	2009-12-03	Study Status
☐	2010-02-18	Study Status Contacts/Locations
☐	2010-07-02	Recruitment Status Study Status
☐	2010-11-18	Study Status
☐	2011-02-11	Study Status Study Design
☐	2011-05-05	Study Status
☐	2011-05-09	Study Status
☐	2012-03-28	Study Status Sponsor/Collaborators Contacts/Locations
☐	2012-06-07	Recruitment Status Study Status
☐	2013-04-16	Study Status Outcome Measures Participant Flow Baseline Characteristics Adverse Events More Information
Date		Changes

Version 7: 2010-11-18

Study Details

Date

Changes

Unique Protocol ID

VGFT-OD-0819

Brief Title

Vascular Endothelial Growth Factor (VEGF) Trap-Eye:
Investigation of Efficacy and Safety in Central Retinal Vein
Occlusion (CRVO)

Official Title

A Randomized, Double Masked, Controlled Phase 3 Study of the
Efficacy, Safety, and Tolerability of Repeated Intravitreal
Administration of Vascular Endothelial Growth Factor Trap-Eye in
Subjects With Macular Edema Secondary to Central Retinal Vein
Occlusion

Secondary IDs

Study Status

Record Verification

2010-11

Overall Status

Active, not recruiting

Study Start

2009-07

Primary Completion

2011-01 [Estimated]

Study Completion

2012-08 [Estimated]

First Submitted
2009-07-10
First Submitted that Met QC Criteria
2009-07-20
First Posted
2009-07-21
Last Update Submitted that Met QC Criteria
2010-11-18
Last Update Posted
2010-11-19 [Estimated]

Sponsor/Collaborator

Sponsor
Regeneron Pharmaceuticals
Responsible Party
Collaborators
Bayer

Oversight

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

Study Description

Brief Summary

This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description

Conditions

Condition

Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords

Macular edema
Retinal vein occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity
Regeneron
COPERNICUS

Study Design

Study Type

Interventional

Primary Purpose

Treatment

Study Phase

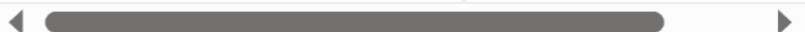
Phase 3

Interventional Study Model

Parallel Assignment
Interventional Model Description
Number of Arms
2
Masking
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Masking Description
Allocation
Randomized
Enrollment
165 [Estimated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2 Monthly intravitreal injection out to the Week 24 P endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week Primary Endpoint



Outcome Measures

Primary Outcome Measures

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment.
[Time Frame: Week 24]

Secondary Outcome Measures

1. Visual acuity
[Time Frame: Week 24]
2. Retinal thickness by OCT
[Time Frame: Week 24]

Eligibility

Minimum Age

18 Years

Maximum Age

Sex

All

Accepts Healthy Volunteers

No

Criteria

Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 μm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.)

- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Central Contact Person

Study Officials

- Name
Robert Vitti, MD
- Role
Study Director
- Affiliation
Regeneron Pharmaceuticals

Location

- Phoenix, Arizona, United States, 85014
- Phoenix, Arizona, United States, 85020
- Tucson, Arizona, United States, 85704
- Arcadia, California, United States, 91007
- Beverly Hills, California, United States, 90211
- La Jolla, California, United States, 92037
- Mountain View, California, United States, 94040
- Oakland, California, United States, 94609
- Sacramento, California, United States, 95841
- Torrance, California, United States, 90503
- New London, Connecticut, United States, 06320
- Altamonte Springs, Florida, United States, 32701
- Fort Lauderdale, Florida, United States, 33334
- Fort Myers, Florida, United States, 33907
- Fort Myers, Florida, United States, 33912
- Miami, Florida, United States, 33143
- Palm Beach Gardens, Florida, United States, 33410

- Winter Haven, Florida, United States, 33880
- Augusta, Georgia, United States, 30909
- Chicago, Illinois, United States, 60612
- Wichita, Kansas, United States, 67214
- Baltimore, Maryland, United States, 21209
- Hagerstown, Maryland, United States, 21740
- Towson, Maryland, United States, 21204
- Boston, Massachusetts, United States, 02114
- Grand Rapids, Michigan, United States, 49525
- Jackson, Michigan, United States, 48104
- Lincoln, Nebraska, United States, 68506
- Las Vegas, Nevada, United States, 89135
- Northfield, New Jersey, United States, 08225
- Toms River, New Jersey, United States, 08755
- Rochester, New York, United States, 14620
- Winston-Salem, North Carolina, United States, 27157
- Cleveland, Ohio, United States, 44195
- Oklahoma City, Oklahoma, United States, 73104
- Portland, Oregon, United States, 97210
- Salem, Oregon, United States, 97302
- Kingston, Pennsylvania, United States, 18704
- Pittsburgh, Pennsylvania, United States, 15213
- West Columbia, South Carolina, United States, 29169
- Rapid City, South Dakota, United States, 57701
- Nashville, Tennessee, United States, 37203
- Abilene, Texas, United States, 79606
- Ft Worth, Texas, United States, 76102
- Houston, Texas, United States, 77030
- San Antonio, Texas, United States, 78240
- Vancouver, British Columbia, Canada, V5Z 3N9
- Victoria, British Columbia, Canada, V8V 4X3
- Halifax, Nova Scotia, Canada, B3H 2Y9
- London, Ontario, Canada, N6A 4V2
- Mississauga, Ontario, Canada, L4W 1W9
- Toronto, Ontario, Canada, M4N 3M5
- Medellin, Antioquia, Colombia
- Bogota, Colombia
- Hyderabad, A.p., India, 500034
- Bangalore, Karnataka, India, 560010
- Kolkata, West Bengal, India, 700073
- Kfar-Saba, Israel, 44281

- Petah Tikva, Israel, 49100
- Rehovot, Israel, 76100
- Tel Aviv, Israel, 64239

IPD Sharing

Available IPD/Information

IPD information

References

Citations

Links

Document Section