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COMPLETED ⓘ

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

ClinicalTrials.gov ID ⓘ NCT01012973

Sponsor ⓘ Bayer

Information provided by ⓘ Bayer (Responsible Party)

Last Update Posted ⓘ 2014-11-02

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.

☐	2009-11-12	None (earliest version on record)
☐	2010-01-21	Study Status Study Description

Compare



		Contacts/Locations Study Identification
☐	2010-02-09	Study Status Contacts/Locations
☐	2010-03-16	Study Identification Study Status Contacts/Locations
☐	2010-04-16	Study Status Contacts/Locations Study Identification
☐	2010-07-22	Study Status Contacts/Locations Eligibility Arms and Interventions
☐	2010-08-25	Study Status Contacts/Locations
☐	2010-08-26	Recruitment Status Study Status
☐	2010-09-08	Study Status
☐	2010-10-04	Study Status
☐	2010-11-01	Study Status
☐	2011-01-25	Study Status Contacts/Locations
☐	2011-04-08	Study Status Study Design
☐	2011-06-23	Study Status

		Eligibility Contacts/Locations Arms and Interventions Outcome Measures
☐	2011-09-19	Study Status
☐	2011-11-29	Study Status Study Identification
☐	2012-01-26	Study Status Contacts/Locations
☐	2012-02-20	Recruitment Status Study Status
☐	2012-10-23	Study Status Baseline Characteristics Arms and Interventions Outcome Measures Participant Flow Adverse Events More Information
☐	2012-12-18	Study Status Arms and Interventions Baseline Characteristics
☐	2013-01-18	Study Status Arms and Interventions Baseline Characteristics
☐	2014-01-30	Study Status Sponsor/Collaborators Contacts/Locations References Baseline Characteristics

2010-11-01 Date		Study Status Changes

Version 11: 2010-11-01

Date

Changes

Study Identification

Unique Protocol ID

14130

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, Sham-controlled Phase 3 Study
of the Efficacy, Safety and Tolerability of Repeated Intravitreal
Administration of VEGF Trap-Eye in Subjects With Macular
Edema Secondary to Central Retinal Vein Occlusion (CRVO)

Secondary IDs

EudraCT: 2009-010973-19

Study Status

Record Verification

2010-11

Overall Status

Date**Changes**

Active, not recruiting

Study Start

2009-10

Primary Completion

2011-02 [Estimated]

Study Completion

2012-03 [Estimated]

First Submitted

-

First Submitted that Met QC Criteria

2009-11-12

First Posted

2009-11-13

Last Update Submitted that Met QC Criteria

2010-11-01

Last Update Posted

2010-11-02 [Estimated]

Sponsor/Collaborator

Sponsor

Bayer

Responsible Party

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Collaborators

Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug

U.S. FDA-regulated Device

Data Monitoring

Yes

Date

Changes

Brief Summary

To determine the efficacy of vascular endothelial growth factor (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

Retinal Vein Occlusion

Keywords

Macular Edema
Central Retinal Vein Occlusion
CRVO
VEGF Trap-Eye
best-corrected visual acuity

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
Triple (Participant, Investigator, Outcomes Assessor)
Masking Description
Allocation
Randomized
Enrollment
165 [Estimated]

Arms and Interventions

Arms	Assigned Interventions ▲
Experimental: Arm 1	Drug: VEGF Trap-Eye (BA - Intravitreal injectic 0 to 20 injection o - Trap-Eye every 4 v - weeks 24 to 52 ev

or neovascularization of the retina elsewhere (NVE) requiring pan-retinal photocoagulation

[Time Frame: Week 24]

4. Change in the NEI-VFQ-25 total score from baseline

[Time Frame: Week 24]

5. Change in the EQ-5D score from baseline

[Time Frame: Week 24]

Eligibility

Minimum Age

18 Years

Maximum Age

Sex

All

Accepts Healthy Volunteers

No

Criteria

Inclusion Criteria:

- Center-involved macular edema secondary to central retinal vein occlusion (CRVO) for no longer than 9 months with mean central subfield thickness ≥ 250 μm on optical coherence tomography (OCT)
- Adults ≥ 18 years
- early treatment diabetic retinopathy study (ETDRS) best corrected visual acuity (BCVA) of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Any prior treatment with anti-VEGF agents in the study eye (Pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc.) or previous administration of systemic anti-angiogenic medications
- 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
Bayer Study Director
- Role
Study Director
- Affiliation
Bayer

Location

- Chatswood, New South Wales, Australia, 2067
- Parramatta, New South Wales, Australia, 2150
- Sydney, New South Wales, Australia, 2000
- Westmead, New South Wales, Australia, 2145
- East Melbourne, Victoria, Australia, 3002
- Nedlands, Western Australia, Australia, 6009
- Innsbruck, Austria, 6020
- Linz, Austria, 4021
- Wien, Austria, 1090
- Paris, Cedex 12, France, 75557
- Nantes, Cedex 1, France, 44093
- Bordeaux, France, 33000
- Dijon, France, 21033
- Marseille, France, 13008
- Paris, France, 75015
- Freiburg, Baden-Württemberg, Germany, 79106
- Heidelberg, Baden-Württemberg, Germany, 69120
- Tübingen, Baden-Württemberg, Germany, 72076
- München, Bayern, Germany, 81675
- Regensburg, Bayern, Germany, 93053
- Darmstadt, Hessen, Germany, 64297

- Frankfurt, Hessen, Germany, 60596
- Göttingen, Niedersachsen, Germany, 37075
- Aachen, Nordrhein-Westfalen, Germany, 52074
- Bonn, Nordrhein-Westfalen, Germany, 53105
- Essen, Nordrhein-Westfalen, Germany, 45122
- Köln, Nordrhein-Westfalen, Germany, 50924
- Münster, Nordrhein-Westfalen, Germany, 48145
- Ludwigshafen, Rheinland-Pfalz, Germany, 67063
- Mainz, Rheinland-Pfalz, Germany, 55131
- Homburg, Saarland, Germany, 66424
- Chemnitz, Sachsen, Germany, 09116
- Dresden, Sachsen, Germany, 01307
- Dresden, Sachsen, Germany, 06067
- Leipzig, Sachsen, Germany, 04103
- Kiel, Schleswig-Holstein, Germany, 24105
- Lübeck, Schleswig-Holstein, Germany, 23538
- Berlin, Germany, 13353
- Hamburg, Germany, 20251
- Marburg, Germany, 35037
- Budapest, Hungary, 1036
- Budapest, Hungary, 1089
- Budapest, Hungary, 1106
- Debrecen, Hungary, 4032
- Veszprem, Hungary, 8200
- Zalaegerszeg, Hungary, H-8900
- Ancona, Italy, 60126
- Bari, Italy, 70124
- Catania, Italy, 95123
- Firenze, Italy, 50134
- Milano, Italy, 20122
- Milano, Italy, 20132
- Milano, Italy, 20157
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- Roma, Italy, 00133
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- Nagoya, Aichi, Japan, 466-8560
- Nagoya, Aichi, Japan, 467-8602
- Urayasu, Chiba, Japan, 279-0021
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- Kungki-do, Korea, Republic of, 463-707
- Seoul, Korea, Republic of, 110 744
- Seoul, Korea, Republic of, 110-744
- Seoul, Korea, Republic of, 138-736
- Seoul, Korea, Republic of
- Riga, Latvia, 1009
- Riga, Latvia, LV-1002
- Singapore, Singapore, 119074
- Singapore, Singapore, 168751

IPD Sharing

Available IPD/Information

IPD information

References

Citations

Links

Document Section