

1/5/2021

History of Changes for Study: NCT01012973

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

[Latest version \(submitted October 27, 2014\) 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 comparison format 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 selected.
- 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	<input checked="" type="radio"/>	<input checked="" type="radio"/>	November 12, 2009	None (earliest Version on record)
2	<input type="radio"/>	<input type="radio"/>	January 21, 2010	Contacts/Locations, Study Status, Study Identification and Study Description

<https://clinicaltrials.gov/ct2/history/NCT01012973?A=1&B=1&C=merged#StudyPageTop>

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Version	A	B	Submitted Date	Changes
3	<input type="radio"/>	<input type="radio"/>	February 9, 2010	Contacts/Locations and Study Status
4	<input type="radio"/>	<input type="radio"/>	March 16, 2010	Contacts/Locations, Study Status and Study Identification
5	<input type="radio"/>	<input type="radio"/>	April 16, 2010	Contacts/Locations, Study Status and Study Identification
6	<input type="radio"/>	<input type="radio"/>	July 22, 2010	Contacts/Locations, Study Status, Eligibility and Arms and Interventions
7	<input type="radio"/>	<input type="radio"/>	August 25, 2010	Study Status and Contacts/Locations
8	<input type="radio"/>	<input type="radio"/>	August 26, 2010	Recruitment Status, Study Status and Contacts/Locations
9	<input type="radio"/>	<input type="radio"/>	September 8, 2010	Study Status
10	<input type="radio"/>	<input type="radio"/>	October 4, 2010	Study Status
11	<input type="radio"/>	<input type="radio"/>	November 1, 2010	Study Status
12	<input type="radio"/>	<input type="radio"/>	January 25, 2011	Study Status and Contacts/Locations
13	<input type="radio"/>	<input type="radio"/>	April 8, 2011	Study Status and Study Design
14	<input type="radio"/>	<input type="radio"/>	June 23, 2011	Arms and Interventions, Study Status, Contacts/Locations and Eligibility
15	<input type="radio"/>	<input type="radio"/>	September 19, 2011	Study Status
16	<input type="radio"/>	<input type="radio"/>	November 29, 2011	Study Status and Study Identification
17	<input type="radio"/>	<input type="radio"/>	January 26, 2012	Study Status and Contacts/Locations
18	<input type="radio"/>	<input type="radio"/>	February 20, 2012	Recruitment Status and Study Status
19	<input type="radio"/>	<input type="radio"/>	October 23, 2012	Outcome Measures, Arms and Interventions, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow
20	<input type="radio"/>	<input type="radio"/>	December 18, 2012	Arms and Interventions, Study Status and Baseline Characteristics

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Version	A	B	Submitted Date	Changes
21	<input type="radio"/>	<input type="radio"/>	January 18, 2013	Arms and Interventions, Study Status and Baseline Characteristics
22	<input type="radio"/>	<input type="radio"/>	January 30, 2014	Contacts/Locations, Sponsor/Collaborators, Study Status, Baseline Characteristics and Referen
23	<input type="radio"/>	<input type="radio"/>	October 27, 2014	Study Status and References

Compare

Comparison Format:

Merged

Side-by-Side

[Scroll up to access the controls](#)

Study NCT01012973

Submitted Date: November 12, 2009 (v1)

Study Identification

Unique Protocol ID: 14130

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Subjects With Macular Edema and 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 and Central Retinal Vein Occlusion (CRVO)

Secondary IDs: EudraCT: 2009-010973-19
GALILEO

Study Status

Record Verification: November 2009

Overall Status: Recruiting

Study Start: October 2009

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Primary Completion: February 2011 [Anticipated]

Study Completion: August 2012 [Anticipated]

First Submitted: October 30, 2009

First Submitted that Met QC Criteria: November 12, 2009

Met QC Criteria:

First Posted: November 13, 2009 [Estimate]

Last Update Submitted that Met QC Criteria: November 12, 2009

Met QC Criteria:

Last Update Posted: November 13, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: To determine the efficacy of vascular endothelial growth factor (VEGF) Trap-Eye injectable on vision function in subjects with macular edema as a consequence of central retinal vein occlusion

Detailed Description:

Conditions

Conditions: Retinal Vein Occlusion

Keywords: Macular Edema

Central Retinal Vein Occlusion

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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
Number of Arms: 2
Masking: Triple (Participant, Investigator, Outcomes Assessor)
Allocation: Randomized
Enrollment: 165 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) Intravitreal injection. Weeks 0 to 20 injection of VEGF Trap-Eye every 4 weeks; weeks 24 to 48 every 4 weeks re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; weeks 52 to 100 safety follow-up.
Sham Comparator: Arm 2	Sham treatment Sham treatment. Weeks 0 to 20 sham treatment; weeks 24 to 48 every 4 weeks re-assessment and either (PRN) injection of VEGF Trap-Eye or sham injection; weeks 52 to 100 safety follow-up.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who gain at least 15 letters in BCVA on the EDTRS chart compared with baseline at the end of the study.

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