

## History of Changes for Study: NCT01012973

### Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in 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"/>	<a href="#">November 12, 2009</a>	None (earliest Version on record)
2	<input type="radio"/>	<input type="radio"/>	<a href="#">January 21, 2010</a>	Contacts/Locations, Study Status, Study Identification and Study Description

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

1/5/2021

History of Changes for Study: NCT01012973

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

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

1/5/2021

History of Changes for Study: NCT01012973

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

#### Study Status

Record Verification: November 2009

Overall Status: Recruiting

Study Start: October 2009

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

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 injection 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

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 injecti Eye every 4 weeks; weeks 24 to 48 every assessment and either (PRN) injection of sham injection; weeks 52 to 100 safety fo
Sham Comparator: Arm 2	Sham treatment Sham treatment. Weeks 0 to 20 sham trea weeks; weeks 24 to 48 every 4 weeks re- sham injection; weeks 52 to 100 safety fo

### 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

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