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History of Changes for Study: NCT01012973

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety i 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-b 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 versio
- 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	◉	◉	November 12, 2009	None (earliest Version on record)
2	○	○	January 21, 2010	Contacts/Locations, Study Status, Study Identification and Study Description

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

Version	A	B	Submitted Date	Changes
21	○	○	January 18, 2013	Arms and Interventions, Study Status and Baseline Characteristics
22	○	○	January 30, 2014	Contacts/Locations, Sponsor/Collaborators, Study Status, Baseline Characteristics and F
23	○	○	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 Retinal Vein Occlusion (CRVO)

Official Title: A Randomized, Double-masked, Sham-controlled Phase 3 Study of the Efficacy, Sa of Repeated Intravitreal Administration of VEGF Trap-Eye in Subjects With Macular 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

Primary Completion:	February 2011 [Anticipated]
Study Completion:	August 2012 [Anticipated]
First Submitted:	October 30, 2009
First Submitted that Met QC Criteria:	November 12, 2009
First Posted:	November 13, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	November 12, 2009
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 inj on vision function in subjects with macular edema as a consequence of central retin
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 fol
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 fol

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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