1/7/2021



ClinicalTrials.gov archive

History of Changes for Study: NCT00509795

Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in Macular Degeneration(AMD) (VIEW1)

<u>Latest version (submitted December 20, 2012) on ClinicalTrials.gov</u>

- · 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-lapplies 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
- 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 | Α | В | Submitted Date | Changes | |
|---------|---------|---------|----------------------|---|--|
| 1 | \circ | \circ | <u>July 31, 2007</u> | None (earliest Version on record) | |
| 2 | \circ | \circ | August 17, 2007 | Recruitment Status, Study Status and Contacts/Locations | |

https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop



| Version | Α | В | Submitted Date | Changes |
|---------|------------|------------|---------------------------|--|
| 3 | \circ | \circ | <u>November 14, 2007</u> | Contacts/Locations and Study Status |
| 4 | \circ | \circ | <u>December 4, 2007</u> | Study Status and Contacts/Locations |
| 5 | 0 | 0 | March 13, 2008 | Study Status and Eligibility |
| 6 | 0 | 0 | June 26, 2008 | Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measure Identification |
| 7 | 0 | 0 | <u>January 22, 2009</u> | Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility Sponsor/Collaborators |
| 8 | O | \circ | March 3, 2009 | Study Status and Contacts/Locations |
| 9 | 0 | • | <u>April 28, 2009</u> | Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Stu |
| 10 | \bigcirc | \bigcirc | <u>September 12, 2009</u> | Recruitment Status, Study Status and Contacts/Locations |
| 11 | \circ | \circ | <u>December 1, 2009</u> | Study Status, Contacts/Locations and Sponsor/Collaborators |
| 12 | \circ | \circ | <u>January 5, 2011</u> | Study Status |
| 13 | 0 | 0 | <u>April 18, 2011</u> | Study Status and Study Design |
| 14 | 0 | 0 | <u>May 4, 2011</u> | Study Status |
| 15 | 0 | 0 | <u>December 1, 2011</u> | Recruitment Status, Study Status and Sponsor/Collaborators |
| 16 | 0 | 0 | <u>April 13, 2012</u> | Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Asseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification |
| 17 | 0 | 0 | December 17, 2012 | Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flor |
| 18 | 0 | 0 | <u>December 20, 2012</u> | Outcome Measures, References and Study Status |



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Comparison Format:



O Side-by-Side

Scroll up to access the controls

Compare v7 to v8

Changes (Merged) for Study: NCT00509795 March 3, 2009 (v8) -- April 28, 2009 (v9)

Changes in: Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study

□ Show only changed modules

Study Identification

Unique Protocol ID: VGFT-OD-0605

Brief Title: Double-Masked Study of Efficacy and Safety of IVT VEGF Trap-Eye in Subjects W

1) (VIEW1) Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of E

Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, S

Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovasci

Macular Degeneration

Secondary IDs:

Study Status

Record Verification: March 2009 April 2009

Overall Status: Recruiting

Study Start: August 2007

Primary Completion: October 2010 December 2011 [Anticipated]

Study Completion: January 2012 December 2011 [Anticipated]

First Submitted: July 31, 2007

https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop



Find authenticated court documents without watermarks at docketalarm.com.

History of Changes for Study: NCT00509795

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First Submitted that July 31, 2007

Met QC Criteria:

First Posted: August 1, 2007 [Estimate]

Last Update Submitted that March 3, 2009 April 28, 2009

Met QC Criteria:

Last Update Posted: March 5 April 29, 2009 [Estimate]

Sponsor/Collaborators

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 study is a phase III, double-masked, randomized, study of the efficacy and saf

Eye in patients with neovascular age-related macular degeneration. Approximately

be randomized in the US and Canada.

Detailed Description:

Conditions

Conditions: Neovascular Age-Related Macular Degeneration

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop



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Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

| Arms | Assigned Interventions |
|------|------------------------|
|------|------------------------|

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