

1/7/2021

History of Changes for Study: NCT00509795



ClinicalTrials.gov archive

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

[Latest version \(submitted December 20, 2012\) 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 type="radio"/>	<input type="radio"/>	July 31, 2007	None (earliest Version on record)
2	<input type="radio"/>	<input type="radio"/>	August 17, 2007	Recruitment Status, Study Status and Contacts/Locations

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

1/7/2021

History of Changes for Study: NCT00509795

Version	A	B	Submitted Date	Changes
3	<input type="radio"/>	<input type="radio"/>	November 14, 2007	Contacts/Locations and Study Status
4	<input type="radio"/>	<input type="radio"/>	December 4, 2007	Study Status and Contacts/Locations
5	<input type="radio"/>	<input type="radio"/>	March 13, 2008	Study Status and Eligibility
6	<input type="radio"/>	<input type="radio"/>	June 26, 2008	Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Measures Identification
7	<input type="radio"/>	<input type="radio"/>	January 22, 2009	Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibility and Sponsor/Collaborators
8	<input checked="" type="radio"/>	<input type="radio"/>	March 3, 2009	Study Status and Contacts/Locations
9	<input type="radio"/>	<input checked="" type="radio"/>	April 28, 2009	Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Study Id
10	<input type="radio"/>	<input type="radio"/>	September 12, 2009	Recruitment Status, Study Status and Contacts/Locations
11	<input type="radio"/>	<input type="radio"/>	December 1, 2009	Study Status, Contacts/Locations and Sponsor/Collaborators
12	<input type="radio"/>	<input type="radio"/>	January 5, 2011	Study Status
13	<input type="radio"/>	<input type="radio"/>	April 18, 2011	Study Status and Study Design
14	<input type="radio"/>	<input type="radio"/>	May 4, 2011	Study Status
15	<input type="radio"/>	<input type="radio"/>	December 1, 2011	Recruitment Status, Study Status and Sponsor/Collaborators
16	<input type="radio"/>	<input type="radio"/>	April 13, 2012	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Baseline Characteristics, Participant Flow, Eligibility, Study Description and Study Identification
17	<input type="radio"/>	<input type="radio"/>	December 17, 2012	Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flow and
18	<input type="radio"/>	<input type="radio"/>	December 20, 2012	Outcome Measures, References and Study Status

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

1/7/2021

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Compare

Comparison Format: Merged
 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 Ident](#)

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 With W~~
~~1)-(VIEW1)~~ *Vascular Endothelial Growth Factor(VEGF) Trap-Eye:Investigation of Efficacy*
Wet Age-Related Macular Degeneration(AMD) (VIEW1)

Official Title: A Randomized, Double Masked, Active Controlled Phase III Study of the Efficacy, Safety,
Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular
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>

1/7/2021

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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 safety of
Eye in patients with neovascular age-related macular degeneration. Approximately 1200
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>

1/7/2021

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

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