History of Changes for Study: NCT00509795

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Vascular Endothelial Growth Factor(VEGF)Trap-Eye:Investigation of Efficacy and Safety in 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-l
 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
- 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

١	Version	Α	в	Submitted Date	Changes
	1	\bigcirc	0	<u>July 31, 2007</u>	None (earliest Version on record)
	2	\bigcirc	0	<u>August 17, 2007</u>	Recruitment Status, Study Status and Contacts/Locations

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

History of Changes for Study: NCT00509795 Version Α в Submitted Date Changes \bigcirc \bigcirc November 14, 2007 3 Contacts/Locations and Study Status 0 Ο 4 December 4, 2007 Study Status and Contacts/Locations \bigcirc \bigcirc 5 March 13, 2008 Study Status and Eligibility 0 0 6 June 26, 2008 Contacts/Locations, Arms and Interventions, Study Design, Study Status, Outcome Mea Identification \bigcirc \bigcirc 7 January 22, 2009 Contacts/Locations, Study Status, Arms and Interventions, Outcome Measures, Eligibilit Sponsor/Collaborators \bigcirc \bigcirc 8 March 3, 2009 Study Status and Contacts/Locations \bigcirc \bigcirc 9 April 28, 2009 Outcome Measures, Arms and Interventions, Study Status, Eligibility, Conditions and Stu 0 0 10 September 12, 2009 Recruitment Status, Study Status and Contacts/Locations \bigcirc \bigcirc December 1, 2009 11 Study Status, Contacts/Locations and Sponsor/Collaborators 0 Ο <u>January 5, 2011</u> 12 Study Status \bigcirc \bigcirc 13 April 18, 2011 Study Status and Study Design 0 \bigcirc 14 May 4, 2011 Study Status \bigcirc \bigcirc December 1, 2011 15 Recruitment Status, Study Status and Sponsor/Collaborators \bigcirc \bigcirc 16 April 13, 2012 Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Baseline Characteristics, Participant Flow, Elig bility, Study Description and Study Identif \bigcirc \bigcirc December 17, 2012 Reported Adverse Events, Outcome Measures, Baseline Characteristics, Participant Flo 17 0 Ο December 20, 2012 18 Outcome Measures, References and Study Status

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1/7/	2021	History of Changes for Study: NCT00509795					
	Compare Comparis	son 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: <u>Outcome Mea</u>	asures, <u>Arms and Interventions, Study Status, Eligibility, Conditions</u> and <u>Stud</u>					
		☐ Show only changed modules					
	Study Identification						
	Unique Protocol ID:	VGFT-OD-0605					
	Brief Title:	Double Masked Study of Efficacy and Safety of IVT VECF 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, Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovasc 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					
http	https://clinicaltrials.gov/ct2/history/NCT00509795?A=8&B=9&C=merged#StudyPageTop						

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History of Changes for Study: NCT00509795

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

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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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