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TERMINATED ⓘ

Management decision

Anecortave Acetate Risk-Reduction Trial (AART)

ClinicalTrials.gov ID ⓘ NCT00307398

Sponsor ⓘ Alcon Research

Information provided by ⓘ Alcon Research (Responsible Party)

Last Update Posted ⓘ 2012-11-28

Study Details Tab

Study Overview

Brief Summary

A 48 month study of posterior juxtasceral administrations of Anecortave Acetate 15 or 30 mg or sham administration every 6 months.

Feedback

Conditions ⓘ

Dry AMD

Intervention / Treatment ⓘ

- Drug: Anecortave Acetate (AL-3789) sterile suspension, 15 mg or 30 mg
- Other: Anecortave Acetate Vehicle

Other Study ID Numbers ⓘ

- C-02-60

Study Start ⓘ

2004-03

Primary Completion (Actual) ⓘ

2009-01

Study Completion (Actual) ⓘ

2009-01

Enrollment (Actual) ⓘ

2596

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine[FDA Drug and Device Resources](https://www.clinicaltrials.gov/fda-links) (<https://www.clinicaltrials.gov/fda-links>).**Contacts and Locations**

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

This study has 1 location

United States

Texas Locations

 **Fort Worth, Texas, United States, 76134**
Study Centers in the United States and
Globally

[Click to view interactive map](#)

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://www.clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- Dry AMD study eye, Wet AMD non-study eye.
- Other protocol-defined inclusion criteria may apply.

Exclusion Criteria:

- Age
- Other protocol-defined exclusion criteria may apply.

Ages Eligible for Study ⓘ

50 Years and older (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm i	Intervention/Treatment i
Experimental: AL-3789 One injection to the study eye by the posterior juxtascleral depot procedure at 6-month intervals for 42 months.	Drug: Anecortave Acetate (AL-3789) sterile suspension, 15 mg or 30 mg One 0.5 mL injection of 30 mg/mL (AA 15 mg) or one 0.5 mL injection of 60 mg/mL (AA 30 mg) into a posterior juxtascleral depot (PJD) at 6-month intervals.
Sham Comparator: Anecortave Acetate Vehicle One sham injection to the study eye at 6-month intervals for 42 months. Syringe containing AA vehicle was not inserted into the eye.	Other: Anecortave Acetate Vehicle One 0.5 mL sham injection at 6-month intervals. Syringe containing AA vehicle was not inserted into the eye.

What is the study measuring?

Primary Outcome Measures i

Outcome Measure	Measure Description	Time Frame
Proportion of patients with sight-threatening choroidal	ST-CNV is defined as CNV or a portion of CNV within 2500 microns of the foveal center, as evidenced by digital angiography at the clinical site.	Month 48

neovascularization (ST-CNV) in the study eye at Month 48		
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Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Alcon Research

Investigators ⓘ

- Study Director: Patricia Zilliox, Study Manager

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2006-03-24

First Submitted that Met QC Criteria ⓘ

2006-03-24

First Posted (Estimated) ⓘ

2006-03-28

Certification/Extension Dates

Certification/Extension First Submitted ⓘ

2012-11-27

Certification/Extension First Submitted that Met QC Criteria ⓘ

2012-11-27

Certification/Extension First Posted (Estimated) ⓘ

2012-11-28

Study Record Updates**Last Update Submitted that met QC Criteria** ⓘ

2012-11-27

Last Update Posted (Estimated) ⓘ

2012-11-28

Last Verified ⓘ

2009-05

More Information**Terms related to this study****Keywords Provided by Alcon Research**

AMD
Dry AMD
Drusen
CNV

Additional Relevant MeSH Terms

Angiogenesis Inhibitors
Angiogenesis Modulating Agents
Growth Substances
Physiological Effects of Drugs
Growth Inhibitors
Antineoplastic Agents
Anti-Inflammatory Agents
Hydrocortisone
Anecortave