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COMPLETED ⓘ

Study of Fenretinide in the Treatment of Geographic Atrophy Associated With Dry Age-Related Macular Degeneration

ClinicalTrials.gov ID ⓘ NCT00429936

Sponsor ⓘ Sirion Therapeutics, Inc.

Information provided by ⓘ Sirion Therapeutics, Inc.

Last Update Posted ⓘ 2010-06-22

Study Details Tab

Study Overview

Brief Summary

The purpose of this phase II study is to determine the efficacy of fenretinide in the treatment of geographic atrophy (GA) in subjects with the dry form of age-related macular degeneration (AMD).

Official Title

A Phase II Multicenter, Randomized, Double-Masked, Placebo-Controlled, Dose-Comparison Study of the Safety and Efficacy of Fenretinide in the Treatment of Geographic Atrophy in Subjects With Age-Related Macular Degeneration

Conditions ⓘ

Geographic Atrophy

Dry Age Related Macular Degeneration

Intervention / Treatment ⓘ



- Drug: Fenretinide

Other Study ID Numbers ⓘ

- SRFR-001

Study Start ⓘ

2006-12

Primary Completion (Actual) ⓘ

2010-05

Study Completion (Actual) ⓘ

2010-05

Enrollment (Actual) ⓘ

245

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (https://medlineplus.gov/genetics/) related topics:

[Age-related macular degeneration](https://medlineplus.gov/genetics/condition/age-related-macular-degeneration) (https://medlineplus.gov/genetics/condition/age-related-macular-degeneration)

[MedlinePlus](https://medlineplus.gov/) (https://medlineplus.gov/) related topics: [Macular Degeneration](https://medlineplus.gov/maculardegeneration.html) (https://medlineplus.gov/maculardegeneration.html).

[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.

No location data

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:

- males or females, 50 to 89 years of age
- must have GA from AMD in one or both eyes

Exclusion Criteria:

- GA due to any disease other than AMD (eg, drug-induced)

Ages Eligible for Study ⓘ

50 Years to 89 Years (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 ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm i	Intervention/Treatment i
Active Comparator: 100 mg fenretinide softgel capsules Three (3) 100-mg fenretinide softgel capsules	Drug: Fenretinide Once daily 30 minutes after the evening meal for 24 months
Active Comparator: Fenretinide and placebo softgel capsules One (1) 100-mg fenretinide softgel capsule and two (2) placebo softgel capsules	Drug: Fenretinide Once daily 30 minutes after the evening meal for 24 months
Placebo Comparator: Placebo softgel capsules Three (3) placebo softgel capsules	Drug: Fenretinide Once daily 30 minutes after the evening meal for 24 months

What is the study measuring?

Primary Outcome Measures i

Outcome Measure	Measure Description	Time Frame
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GA lesion progression		1 year
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Collaborators and Investigators

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

Sponsor ⓘ

Sirion Therapeutics, Inc.

Collaborators ⓘ

- ReVision Therapeutics, Inc.

Investigators ⓘ

- Study Director: Roger Vogel, MD, ReVision Therapeutics Advisor

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- [Yeong JL, Loveman E, Colquitt JL, Royle P, Waugh N, Lois N. Visual cycle modulators versus placebo or observation for the prevention and treatment of geographic atrophy due to age-related macular degeneration. Cochrane Database Syst Rev. 2020 Dec 17;12\(12\):CD013154. doi: 10.1002/14651858.CD013154.pub2.](https://pubmed.ncbi.nlm.nih.gov/3331670/) (https://pubmed.ncbi.nlm.nih.gov/3331670/)

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 ⓘ

2007-01-30

First Submitted that Met QC Criteria ⓘ

2007-01-31

First Posted (Estimated) ⓘ

2007-02-01

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2010-06-21

Last Update Posted (Estimated) ⓘ

2010-06-22

Last Verified ⓘ

2010-06

More Information

Terms related to this study

Keywords Provided by Sirion Therapeutics, Inc.

Dry Age Related Macular Degeneration
Geographic Atrophy

Additional Relevant MeSH Terms

Retinal Degeneration
Retinal Diseases
Eye Diseases
Pathological Conditions, Anatomical
Macular Degeneration
Geographic Atrophy
Atrophy

Antineoplastic Agents

Anticarcinogenic Agents

Protective Agents

Physiological Effects of Drugs

Fenretinide