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UNKNOWN STATUS 

The OMEGA Study: Use of Eye Drops to Treat Geographic Atrophy Associated With Age-Related Macular Degeneration (Dry AMD) (OMEGA)

ClinicalTrials.gov ID  NCT00485394

Sponsor  Othera Pharmaceuticals

Information provided by  Othera Pharmaceuticals

Last Update Posted  2008-04-02

Study Details Tab

Study Overview

Brief Summary

The purpose of this trial is to compare the ability of two doses of OT-551 ophthalmic solution and drug-free solution to safely and effectively treat geographic atrophy associated with age-related macular degeneration.

Detailed Description

Age-related macular degeneration (AMD) results in severe, irreversible central vision loss and is the leading cause of blindness in individuals older than 50 years in the western world. The vast majority of AMD patients have the 'dry' (non-exudative) form that is characterized by the presence of drusen and atrophic changes in the retinal pigment epithelium (RPE). Dry AMD may remain static or progress slowly to produce areas of geographic atrophy (GA), the advanced or late-stage form of dry AMD. GA is a severe vision-threatening lesion of the macula that may impair visual function, impact daily life activities, and result in blindness. Currently, there is no approved treatment for dry AMD or GA. Pre-



clinical results have shown that OT-551 may protect RPE cells and photoreceptors from oxidative damage and block angiogenesis stimulated by VEGF and other growth factors, and therefore is a therapeutic candidate for treating GA.

Official Title

A Randomized, Double-Masked, Dose-Ranging, Multi-Center, Phase II Study Comparing the Safety and Efficacy of OT-551 With Placebo to Treat Geographic Atrophy Associated With Age-Related Macular Degeneration

Conditions ⓘ

Age-Related Macular Degeneration

Intervention / Treatment ⓘ

- Drug: OT-551
- Drug: OT-551
- Drug: vehicle placebo

Other Study ID Numbers ⓘ

- OT-551-C04

Study Start ⓘ

2007-06

Primary Completion (Estimated) ⓘ

2010-02

Enrollment (Estimated) ⓘ

198

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.

This study has 18 locations

United States

Arizona Locations

-  Mesa, Arizona, United States
-  Tucson, Arizona, United States

California Locations

-  Beverly Hills, California, United States
-  Oxnard, California, United States

[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) (<https://www.clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- have a clinical diagnosis of GA in one or both eyes;
- be of non-childbearing potential

Exclusion Criteria:

- have GA secondary to any condition other than AMD in the study eye;
- have a BCVA of 20/200 or worse in the non-study eye;
- have a history of or current choroidal neovascularization in either eye, or the need for any study eye anti-angiogenic therapy;
- have any ocular condition in the study eye that would progress during the course of the study and could affect central vision or other ocular conditions that may be a confounding factor in this study;
- need to wear contact lenses in the study eye during the study;
- had confounding ocular surgery in the study eye;
- have concomitant treatment with any systemic or ocular medication that is known to be toxic to the lens, retina, or optic nerve;

Ages Eligible for Study ⓘ

55 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 ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: 1 OT-551 0.3% ophthalmic solution	Drug: OT-551 • OT-551 0.3% ophthalmic solution, 2 drops 4 times daily
Experimental: 2 OT-551 0.45% ophthalmic solution	Drug: OT-551 • OT-551 0.45% ophthalmic solution, 2 drops 4 times daily
Placebo Comparator: 3 vehicle placebo	Drug: vehicle placebo • OT-551 0% ophthalmic solution, 2 drops 4 times daily

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
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Change in the area of GA		2 years
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Collaborators and Investigators

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

Sponsor ⓘ

Othera Pharmaceuticals

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 ⓘ

2007-06-11

First Submitted that Met QC Criteria ⓘ

2007-06-11

First Posted (Estimated) ⓘ

2007-06-13

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2008-03-31

Last Update Posted (Estimated) ⓘ

2008-04-02

Last Verified ⓘ

2008-03

More Information

Terms related to this study

Keywords Provided by Othera Pharmaceuticals

AMD

age-related macular degeneration

geographic atrophy

GA

Additional Relevant MeSH Terms

Retinal Degeneration

Retinal Diseases

Eye Diseases

Pathological Conditions, Anatomical

Macular Degeneration

Geographic Atrophy

Atrophy