

## COVID-19 Information

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*ClinicalTrials.gov*



Trial record **2 of 3** for: fovista | Phase 3

[Previous Study](#) | [Return to List](#) | [Next Study](#)

## A Phase 3 Safety and Efficacy Study of Fovista® (E10030) Intravitreal Administration in Combination With Lucentis® Compared to Lucentis® Monotherapy



The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

ClinicalTrials.gov Identifier: NCT01940900

[Recruitment Status](#) ⓘ : Terminated

[First Posted](#) ⓘ : September 12, 2013

[Results First Posted](#) ⓘ : August 15, 2018

[Last Update Posted](#) ⓘ : August 15, 2018

### Sponsor:

Ophthotech Corporation

### Information provided by (Responsible Party):

Samsung v. Regeneron  
IPR2023-00442  
U.S. Pat. 10,130,681  
Exhibit 2310

[Study Details](#)

[Tabular View](#)

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## Study Description

Go to 

### Brief Summary:

The objectives of this study are to evaluate the safety and efficacy of intravitreal administration of **Fovista®** administered in combination with Lucentis® compared to Lucentis® monotherapy in subjects with subfoveal choroidal neovascularization secondary to age-related macular degeneration (AMD).

| <a href="#">Condition or disease</a> ⓘ | <a href="#">Intervention/treatment</a> ⓘ                                      | <a href="#">Phase</a> ⓘ |
|----------------------------------------|-------------------------------------------------------------------------------|-------------------------|
| Age-Related Macular Degeneration       | Drug: E10030<br>Drug: ranibizumab<br>Drug: E10030 sham intravitreal injection | <b>Phase 3</b>          |

### Detailed Description:

Subjects will be randomized in a 1:1 ratio to the following dose groups:

- Fovista® 1.5 mg/eye + Lucentis® 0.5 mg/eye
- Fovista® sham + Lucentis® 0.5 mg/eye

Subjects will be treated for a total of 24 months with active Fovista® or sham in combination with Lucentis® with the primary endpoint at 12 months.

### Primary Efficacy Endpoint:

The primary efficacy endpoint is the mean change in visual acuity (ETDRS letters) from baseline at the month 12 visit.

### Safety Endpoints:

Safety endpoints include adverse events, vital signs, ophthalmic variables [ophthalmic examination, intraocular pressure (IOP), fluorescein angiogram (FA), optical coherence tomography (OCT)], ECG, and laboratory variables.

Approximately 622 subjects will be randomized into one of the two treatment cohorts (311 patients per dose group).

## Study Design

Go to 

### [Study Type](#) ⓘ :

Interventional (Clinical Trial)

**Actual Enrollment ⓘ :**

627 participants

**Allocation:**

Randomized

**Intervention Model:**

Parallel Assignment

**Masking:**

Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

**Primary Purpose:**

Treatment

**Official Title:**

A Phase 3 Randomized, Double-masked, Controlled Trial to Establish the Safety and Efficacy of Intravitreal Administration of **Fovista®** (Anti PDGF-B Pegylated Aptamer) Administered in Combination With Lucentis® Compared to Lucentis® Monotherapy in Subjects With Subfoveal Neovascular Age-related Macular Degeneration.

**Study Start Date ⓘ :**

August 2013

**Actual Primary Completion Date ⓘ :**

December 2016

**Actual Study Completion Date ⓘ :**

December 2016

**Resource links provided by the National Library of Medicine**[MedlinePlus Genetics](#) related topics: [Age-related macular degeneration](#)[MedlinePlus](#) related topics: [Macular Degeneration](#)[Drug Information](#) available for: [Ranibizumab](#)[U.S. FDA Resources](#)**Arms and Interventions**

Go to

**Arm ⓘ****Intervention/treatment ⓘ**

| Arm                                       | Intervention/treatment                                                           |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Experimental: E10030 + ranibizumab<br>E10030 1.5 mg intravitreal injection +<br>ranibizumab 0.5 mg intravitreal injection  | Drug: E10030<br>Other Name: <b>Fovista®</b><br><br>Drug: ranibizumab<br>Other Name: Lucentis®                                                                       |
| Active Comparator: Sham + ranibizumab<br>E10030 sham intravitreal injection + ranibizumab<br>0.5 mg intravitreal injection | Drug: ranibizumab<br>Other Name: Lucentis®<br><br>Drug: E10030 sham intravitreal injection<br>Pressure on the eye with a syringe with no needle<br>Other Name: Sham |

## Outcome Measures

Go to 

### Primary Outcome Measures :

#### 1. Mean Change in Visual Acuity From Baseline to 12 Months [ Time Frame: 12 Months ]

The primary efficacy endpoint is the mean change in visual acuity (ETDRS letters) from baseline to the month 12 visit. Higher ETDRS letters represents higher vision and a higher change in ETDRS letters represents better functioning.

## Eligibility Criteria

Go to 

### Information from the National Library of Medicine



*Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).*

**Ages Eligible for Study:**

50 Years and older (Adult, Older Adult)

**Sexes Eligible for Study:**

All

**Accepts Healthy Volunteers:**

No

**Criteria****Inclusion Criteria:**

- Subjects of either gender aged  $\geq 50$  years
- Active subfoveal choroidal neovascularization (CNV) secondary to AMD
- Presence of sub-retinal hyper-reflective material (SD-OCT)

**Exclusion Criteria:**

- Any prior treatment for AMD in the study eye prior to the Day 1 visit, except oral supplements of vitamins and minerals
- Any prior intravitreal treatment in the study eye prior to the Day 1 visit, regardless of indication (including intravitreal corticosteroids)
- Any intraocular surgery or thermal laser within three (3) months of trial entry. Any prior thermal laser in the macular region, regardless of indication
- Subjects with subfoveal scar or subfoveal atrophy are excluded
- Diabetes mellitus

**Contacts and Locations**

Go to 

**Information from the National Library of Medicine**

*To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.*

*Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT01940900***

**Locations**

► Show 121 study locations

**Sponsors and Collaborators**

## More Information

Go to 

**Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):**

[Park EJ, Choi J, Lee KC, Na DH. Emerging PEGylated non-biologic drugs. Expert Opin Emerg Drugs. 2019 Jun;24\(2\):107-119. doi: 10.1080/14728214.2019.1604684. Epub 2019 Apr 19. Review.](#)

### Responsible Party:

Ophthotech Corporation

### ClinicalTrials.gov Identifier:

[NCT01940900](#) [History of Changes](#)

### Other Study ID Numbers:

OPH1003

### First Posted:

September 12, 2013 [Key Record Dates](#)

### Results First Posted:

August 15, 2018

### Last Update Posted:

August 15, 2018

### Last Verified:

August 2018

### Individual Participant Data (IPD) Sharing Statement:

#### Plan to Share IPD:

No

#### Plan Description:

There is no plan to share individual participant data at this time

### Keywords provided by Ophthotech ( Ophthotech Corporation ):

Wet AMD

choroidal neovascularization

**Fovista®**

E10030

Lucentis®

**Additional relevant MeSH terms:**

Macular Degeneration  
Retinal Degeneration  
Retinal Diseases  
Eye Diseases  
Ranibizumab  
Angiogenesis Inhibitors  
Angiogenesis Modulating Agents  
Growth Substances  
Physiological Effects of Drugs  
Growth Inhibitors  
Antineoplastic Agents