A clinical study of OPT-302 with aflibercept compared to aflibercept alone in patients with neovascular age-related macular degeneration

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	998
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	tratamiento, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2024-512880-30-00 (CTIS)

Cod. Protocolo
OPT-302-1005

Transicionado 2020-004694-46

Área terapéutica
Enfermedades [C] - Patología ocular [C11]|

Enfermedad investigada
Neovascular Age-related Macular Degeneration (wet AMD)

Título Científico
A Phase 3, Multicentre, Double-masked, Randomised Study to Evaluate the Efficacy and Safety of Intravitreal OPT-302 in Combination with Aflibercept, Compared with Aflibercept Alone, in Participants with Neovascular Age-related Macular Degeneration (nAMD)

Justificación

No aportado

Objetivo Principal

To determine the efficacy of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 2.0 mg aflibercept, in participants with neovascular AMD

Variables de Evaluación Primaria

Mean change from Baseline to Week 52 in Early Treatment Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) letters.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary objectives of the study are to determine the effects of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 2.0 mg aflibercept from Baseline to (and at) Week 52 as determined by: Efficacy: Changes in ETDRS BCVA letter score

Variables de Evaluación Secundaria

Efficacy: - Proportion of participants gaining 15 or more ETDRS BCVA letters from Baseline to Week 52 - Proportion of participants gaining 10 or more ETDRS BCVA letters from Baseline to Week 52
- Change in CNV area by fluorescein angiography (FA) from Baseline to Week 52 - Proportion of participants with absence of both SRF and IR cysts by spectral domain optical coherence tomography (SD-OCT) at Week 52

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male or female participants at least 50 years of age.
2. Active subfoveal CNV lesion or juxtafoveal CNV lesion with foveal involvement that is secondary to AMD in the Study Eye.

3. An ETDRS BCVA score between 60 and 25 (inclusive) letters in the Study Eye.

Criterios de Exclusión

Study Eye Any previous treatment for neovascular AMD.
Clinically significant ocular disorders (other than neovascular AMD), which may interfere with assessment of BCVA, assessment of safety, or fundus imaging.

Calendario

(Última actualización: 28/05/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/07/2021	02/11/2021	08/03/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
13/02/2024	31/03/2025	No aportado	No aportado	No aportado

Promotor

Opthea Limited Australia

650 Chapel Street

Contact Person

Clinical Trial Information

+610398260399

Daniel.Ranayhossaini@opthea.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Cerrado (21/05/2025)

FISABIO

Valencia

VALENCIA

Oftalmología

Cerrado (20/05/2025)

HOSPITAL CLINICO UNIVERSITARIO LOZANO BLESA

Zaragoza

ZARAGOZA

Cerrado (07/05/2024)

HOSPITAL HLA UNIVERSITARIO MONCLOA

Madrid

MADRID

Cerrado (19/05/2025)

HOSPITAL UNIVERSITARI DE BELLVITGE

Hospitalet de Llobregat, L'

BARCELONA

Cerrado (30/05/2025)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Cerrado (27/05/2025)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Cerrado (28/06/2022)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

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Majadahonda

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Cerrado (14/05/2025)

Institut Català de Retina

Barcelona

BARCELONA

Oftalmología

Cerrado (08/05/2025)

INSTITUTO OFTALMOLOGICO FERNANDEZ-VEGA

Oviedo

ASTURIAS

Medicamentos

Eylea 40 mg/mL solution for injection in pre-filled syringe
SOLUTION FOR INJECTION
INTRAVITREAL USE

Código ATC: S01LA05 - AFLIBERCEPT
Principios Activos: N/A

Experimental

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INTRAVITREAL USE

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Código ATC: S01LA05 - AFLIBERCEPT
Principios Activos: N/A

Experimental

OPT-302
SOLUTION FOR INJECTION
INTRAVITREAL USE

-
Principios Activos: N/A

Experimental

Sin resultados

A clinical study of OPT-302 with aflibercept compared to aflibercept alone in patients with neovascular age-related macular degeneration

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	998
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	treatment, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2024-512880-30-00 (CTIS)

Protocol Code
OPT-302-1005

Transitioned 2020-004694-46

Therapeutic area
Diseases [C] - Eye Diseases [C11]|

Investigated Disease
Neovascular Age-related Macular Degeneration (wet AMD)

Scientific Title
A Phase 3, Multicentre, Double-masked, Randomised Study to Evaluate the Efficacy and Safety of Intravitreal OPT-302 in Combination with Aflibercept, Compared with Aflibercept Alone, in Participants with Neovascular Age-related Macular Degeneration (nAMD)

Rationale

Not provided

Main Objective

To determine the efficacy of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 2.0 mg aflibercept, in participants with neovascular AMD

Primary Endpoints

Mean change from Baseline to Week 52 in Early Treatment Retinopathy Study (ETDRS) best-corrected visual acuity (BCVA) letters.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary objectives of the study are to determine the effects of intravitreal 2.0 mg OPT-302 when administered in combination with intravitreal 2.0 mg aflibercept from Baseline to (and at) Week 52 as determined by: Efficacy: Changes in ETDRS BCVA letter score

Secondary Endpoints

Efficacy: - Proportion of participants gaining 15 or more ETDRS BCVA letters from Baseline to Week 52 - Proportion of participants gaining 10 or more ETDRS BCVA letters from Baseline to Week 52
- Change in CNV area by fluorescein angiography (FA) from Baseline to Week 52 - Proportion of participants with absence of both SRF and IR cysts by spectral domain optical coherence tomography (SD-OCT) at Week 52

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male or female participants at least 50 years of age.
2. Active subfoveal CNV lesion or juxtafoveal CNV lesion with foveal involvement that is secondary to AMD in the Study Eye.

3. An ETDRS BCVA score between 60 and 25 (inclusive) letters in the Study Eye.

Exclusion criteria

Study Eye Any previous treatment for neovascular AMD.
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Calendar

(Last Update: 28/05/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/07/2021	02/11/2021	08/03/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
13/02/2024	31/03/2025	Not aported	Not aported	Not aported

Sponsor

Opthea Limited Australia

650 Chapel Street

Contact Person

Clinical Trial Information

+610398260399

Daniel.Ranayhossaini@opthea.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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917044160

Sites

Closed (21/05/2025)

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ATC code: S01LA05 - AFLIBERCEPT
Active Principles: N/A

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INTRAVITREAL USE

ATC code: S01LA05 - AFLIBERCEPT
Active Principles: N/A

Experimental

OPT-302
SOLUTION FOR INJECTION
INTRAVITREAL USE

-

Active Principles: N/A

Experimental

No results