A Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Choroidal Neovascularization Secondary to Pathologic Myopia

Estado
EC Finalizado

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase III

Participantes esperados
280

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Multicéntrico internacional

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
NO

Información

Identificador
2023-506707-25-00 (CTIS)

Cod. Protocolo
CR44829

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

Enfermedad investigada
Choroidal neovascularization secondary to pathologic myopia

Título Científico
A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Choroidal Neovascularization Secondary to Pathologic Myopia

Justificación

No aportado

Objetivo Principal

1. To evaluate the efficacy of intravitreal (IVT) injections of faricimab compared with ranibizumab

Variables de Evaluación Primaria

1. Change from baseline in BCVA averaged over Weeks 4, 8, and 12

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To evaluate the efficacy of faricimab compared with ranibizumab on best-corrected visual acuity (BCVA) outcomes
2. To evaluate the frequency of faricimab administration compared with ranibizumab
3. To evaluate the efficacy of faricimab compared with ranibizumab on anatomic outcomes using optical coherence tomography (OCT)
4. To evaluate the efficacy of faricimab compared with ranibizumab on anatomic outcomes using color fundus photography/fundus fluorescein angiography (CFP/FFA)
5. To evaluate the safety of faricimab compared with ranibizumab
6. To evaluate the immune response to faricimab

Variables de Evaluación Secundaria

1. Change from baseline in BCVA over time
2. Proportion of patients gaining 15 letters averaged over Weeks 4, 8, and 12
3. Proportion of patients gaining 15 letters in BCVA from baseline over time
4. Proportion of patients avoiding loss of 15 letters in BCVA from baseline over time
5. Proportion of patients gaining 15 letters or achieving BCVA of 84 letters over time
6. Proportion of patients with BCVA Snellen equivalent of 20/40 or better over time
7. Proportion of patients with BCVA Snellen equivalent of 20/200 or worse over time
8. Proportion of patients only receiving one injection from baseline to Week 12
9. Proportion of patients only receiving one injection from baseline to Week 24
10. Proportion of patients only receiving one injection from baseline to Week 48
11. Number of IVT injections received by Week 12
12. Number of IVT injections received by Week 24
13. Number of IVT injections received by Week 48
14. Change from baseline in central subfield thickness (CST) of the study eye averaged over Weeks 4, 8, and 12
15. Change from baseline in CST of the study eye over time

16. Change from baseline in total area of CNV lesion at Week 12 and Week 48
17. Change from baseline in total area of CNV leakage at Week 12 and Week 48
18. Proportion of patients with absence of macular leakage at Week 12 and Week 48
19. Incidence and severity of ocular adverse events
20. Incidence and severity of non-ocular adverse events
21. Prevalence of ADAs at baseline and incidence of ADA during the study
22. Relationship between ADA status and efficacy or safety endpoints

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Overtly healthy as determined by medical evaluation that includes medical history, physical examination, and laboratory tests 2. Treatment-naïve choroidal neovascularization (CNV) secondary to myopia 3. Diagnosis of active myopic CNV in the study eye confirmed by ocular examination and CRC review 4. BCVA of 78 to 24 letters, inclusive (20/32 to 20/320 approximate Snellen equivalent), using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol and assessed at the initial testing distance of 4 meters (see the BCVA manual for additional details) on Day 1 5. Presence of at least 1 of the following lesion types (determined by CRC): Subfoveal (presence of abnormal neovasculature in the avascular central fovea) Juxtafoveal (presence of abnormal neovasculature not under the center of the fovea but 200 um from the center) with involvement of the central macular area Extrafoveal (presence of abnormal neovasculature > 200 um from the center of the fovea) with involvement of the central macular area Margin of the optic disc (presence of abnormal neovasculature at peripapillary area) with involvement of the central macular area 6. Sufficiently clear ocular media and adequate pupillary dilatation to allow acquisition of good quality retinal images to confirm diagnosis

Criterios de Exclusión

1. CNV due to causes other than pathologic myopia, such as neovascular age-related macular degeneration, ocular histoplasmosis, trauma, angioid streaks, choroidal rupture, or uveitis, etc
2. Any history of macular pathology unrelated to pathologic myopia affecting vision or contributing to the presence of intraretinal or subretinal fluid
3. Presence at screening of central serous chorioretinopathy or myopic tractional maculopathy. Retinal pigment epithelial tear involving the macula on Day 1
4. Non-functioning non-study eye, defined as either: BCVA Snellen equivalent of 20/200 or worse No physical presence of non-study eye (i.e., monocular)
5. Prior IVT administration of faricimab in either eye
6. History of idiopathic or autoimmune-associated uveitis in either eye. Active ocular inflammation (anterior, intermediate or posterior uveitis, grade trace or above) or suspected or active ocular or periocular infection in either eye on Day 1

Calendario

(Última actualización: 04/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/03/2024	30/05/2024	04/06/2024	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
20/06/2025	No aportado	No aportado	05/03/2026	22/05/2026

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

presidenciaceic@bellvitgehospital.cat

Centros

Activo (07/11/2024)

Bellvitge University Hospital

L'hospitalet De Llobregat

BARCELONA

Ophtalmology

Activo (10/06/2024)

Clinica De Oftalmologia De Cordoba S.L.

Cordoba

CÓRDOBA

Ophtalmology

Activo (05/06/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Ophtalmology

No iniciado (--/--/----)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Medical Retina and Ocular Diabetes Unit

Activo (04/07/2024)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Ophthalmology

Cerrado (11/12/2024)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Ophtalmology

Activo (10/01/2025)

Instituto De Microcirugia Ocular Dos S.L.

Barcelona

BARCELONA

Ophtalmology

Activo (30/05/2024)

Oftalmologia Vistahermosa S.L.

Burjassot

VALENCIA

Ophtalmology

Medicamentos

FARICIMAB
SOLUTION FOR INJECTION
INTRAVITREAL USE

-

Principios Activos: N/A

Experimental

Lucentis 10 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVITREAL USE

Código ATC: S01LA04 - RANIBIZUMAB
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Choroidal Neovascularization Secondary to Pathologic Myopia

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	280
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness	NO

Information

Identifier
2023-506707-25-00 (CTIS)

Protocol Code
CR44829

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

Investigated Disease
Choroidal neovascularization secondary to pathologic myopia

Scientific Title
A Phase III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Choroidal Neovascularization Secondary to Pathologic Myopia

Rationale

Not provided

Main Objective

1. To evaluate the efficacy of intravitreal (IVT) injections of faricimab compared with ranibizumab

Primary Endpoints

1. Change from baseline in BCVA averaged over Weeks 4, 8, and 12

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To evaluate the efficacy of faricimab compared with ranibizumab on best-corrected visual acuity (BCVA) outcomes
2. To evaluate the frequency of faricimab administration compared with ranibizumab
3. To evaluate the efficacy of faricimab compared with ranibizumab on anatomic outcomes using optical coherence tomography (OCT)
4. To evaluate the efficacy of faricimab compared with ranibizumab on anatomic outcomes using color fundus photography/fundus fluorescein angiography (CFP/FFA)
5. To evaluate the safety of faricimab compared with ranibizumab
6. To evaluate the immune response to faricimab

Secondary Endpoints

1. Change from baseline in BCVA over time
2. Proportion of patients gaining 15 letters averaged over Weeks 4, 8, and 12
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4. Proportion of patients avoiding loss of 15 letters in BCVA from baseline over time
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20. Incidence and severity of non-ocular adverse events
21. Prevalence of ADAs at baseline and incidence of ADA during the study
22. Relationship between ADA status and efficacy or safety endpoints

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Overtly healthy as determined by medical evaluation that includes medical history, physical examination, and laboratory tests 2. Treatment-naïve choroidal neovascularization (CNV) secondary to myopia 3. Diagnosis of active myopic CNV in the study eye confirmed by ocular examination and CRC review 4. BCVA of 78 to 24 letters, inclusive (20/32 to 20/320 approximate Snellen equivalent), using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol and assessed at the initial testing distance of 4 meters (see the BCVA manual for additional details) on Day 1 5. Presence of at least 1 of the following lesion types (determined by CRC): Subfoveal (presence of abnormal neovasculature in the avascular central fovea) Juxtafoveal (presence of abnormal neovasculature not under the center of the fovea but 200 um from the center) with involvement of the central macular area Extrafoveal (presence of abnormal neovasculature > 200 um from the center of the fovea) with involvement of the central macular area Margin of the optic disc (presence of abnormal neovasculature at peripapillary area) with involvement of the central macular area 6. Sufficiently clear ocular media and adequate pupillary dilatation to allow acquisition of good quality retinal images to confirm diagnosis

Exclusion criteria

1. CNV due to causes other than pathologic myopia, such as neovascular age-related macular degeneration, ocular histoplasmosis, trauma, angioid streaks, choroidal rupture, or uveitis, etc
2. Any history of macular pathology unrelated to pathologic myopia affecting vision or contributing to the presence of intraretinal or subretinal fluid
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5. Prior IVT administration of faricimab in either eye
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Calendar

(Last Update: 04/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/03/2024	30/05/2024	04/06/2024	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
20/06/2025	Not aported	Not aported	05/03/2026	22/05/2026

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari de Bellvitge

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Sites

Active (07/11/2024)

Bellvitge University Hospital

L'hospitalet De Llobregat

BARCELONA

Ophtalmology

Active (10/06/2024)

Clinica De Oftalmologia De Cordoba S.L.

Cordoba

CÓRDOBA

Ophtalmology

Active (05/06/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Ophtalmology

not initialized (--/--/----)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Medical Retina and Ocular Diabetes Unit

Active (04/07/2024)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Ophthalmology

Closed (11/12/2024)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Ophtalmology

Active (10/01/2025)

Instituto De Microcirugia Ocular Dos S.L.

Barcelona

BARCELONA

Ophtalmology

Active (30/05/2024)

Oftalmologia Vistahermosa S.L.

Burjassot

VALENCIA

Ophtalmology

Medication

FARICIMAB
SOLUTION FOR INJECTION
INTRAVITREAL USE

-

Active Principles: N/A

Experimental

Lucentis 10 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVITREAL USE

ATC code: S01LA04 - RANIBIZUMAB
Active Principles: N/A

Experimental

No results