A Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Ocrelizumab in Adult Patients with Primary Progressive Multiple Sclerosis

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	688
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2022-502611-10-00 (CTIS)

Cod. Protocolo
GN41791

Transicionado 2019-003919-53

Área terapéutica
Enfermedades [C] - Sistema Nervioso [C10]|

Enfermedad investigada
Primary Progressive Multiple Sclerosis (PPMS)

Título Científico
A Phase III Multicenter, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Ocrelizumab in Adult Patients with Primary Progressive Multiple Sclerosis

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of fenebrutinib compared with ocrelizumab in patients with PPMS regardless of adherence to randomized treatment

Variables de Evaluación Primaria

1. Time to onset of composite 12-week confirmed disability progression (cCDP12)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of fenebrutinib treatment compared with ocrelizumab
To evaluate the safety of fenebrutinib compared with ocrelizumab
To characterize the fenebrutinib PK profile

Variables de Evaluación Secundaria

1. Time to onset of composite 24 week CDP (cCDP24)
2. Time to onset of 12-week CDP (CDP12)
3. Time to onset of 24 week CDP (CDP24)
4. Percent change in total brain volume from Week 24 as assessed by MRI scan
5. Percent change from screening to Week 120 in serum neurofilament light chain (NfL) levels
6. Change patient-reported physical impacts of MS (as measured by Multiple Sclerosis Impact Scale, 29-Item [MSIS-29] physical scale)
7. Time to onset of 12 week confirmed 4 point worsening in Symbol Digit Modality Test (SDMT) score
8. The nature, frequency, timing, and severity of adverse events; serious adverse events; and adverse events leading to study treatment withdrawal
9. Change from baseline in targeted vital signs
10. Change from baseline in targeted ECG parameters
11. Change from baseline in clinical laboratory results following study treatment administration
12. Change from baseline in the proportion of patients with suicidal ideation or behavior, as assessed by Columbia Suicide Severity Rating Scale (C-SSRS)
13. Plasma concentration of fenebrutinib at specified timepoints

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Ability to comply with the study protocol
A diagnosis of PPMS in accordance to the revised 2017 McDonald Criteria
Disability progression in the 12 months prior to screening, as assessed by the Pre-Baseline Disability Progression Questionnaire
EDSS score from 3.0 to 6.5 inclusive at screening
Pyramidal functional subscore 2 at screening
For patients currently receiving proton pump inhibitors (PPIs) or H2 receptor antagonists (H2RAs): treatment at a stable dose during the screening period prior to the initiation of study treatment and plans to remain at a stable dose for the duration of study treatment

Criterios de Exclusión

For patients enrolled in Germany and in Italy only: Presence of T1Gd + lesion on the screening MRI
Any known or suspected active infection at screening or baseline, (excluding onychomycosis) or any major episode of infection requiring hospitalization or treatment with IV antimicrobials within 8 weeks prior to and during screening or treatment with oral antimicrobials within 2 weeks prior to and during screening Onychomycosis is not exclusionary unless it is being treated with systemic therapy.
History of confirmed or suspected progressive multifocal leukoencephalopathy (PML)
Patients with a previous history of a serious IRR and/or any hypersensitivity reaction to ocrelizumab
History of cancer, including hematologic malignancy and solid tumors, within 10 years of screening
Immunocompromised state

Calendario

(Última actualización: 21/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
21/01/2021	26/03/2021	19/04/2021	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
21/04/2023	No aportado	No aportado	No aportado	No aportado

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 Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

ceic@vhir.org

934894010

Centros

Cerrado (07/05/2021)

COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA

Coruña, A

CORUÑA

Activo (26/03/2021)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

Vigo

PONTEVEDRA

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

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Neurología

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

Hospital Universitari Arnau De Vilanova De La Gerencia Territorial De Lleida

Lleida

LÉRIDA

Neurología

Activo (02/07/2021)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

Activo (04/08/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

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

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Neurología

Activo (04/11/2021)

Hospital Universitario Puerta Del Mar

Cádiz

CÁDIZ

Activo (26/03/2021)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Activo (16/06/2021)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Activo (12/05/2021)

Hospital Universitario Regional De Malaga

Málaga

MÁLAGA

Activo (08/09/2021)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Medicamentos

Fenebrutinib
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Ocrevus 300 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L04AA36 - OCRELIZUMAB
Principios Activos: N/A

Experimental

Ocrevus 300 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L04AA36 - OCRELIZUMAB
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Ocrelizumab in Adult Patients with Primary Progressive Multiple Sclerosis

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	688
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2022-502611-10-00 (CTIS)

Protocol Code
GN41791

Transitioned 2019-003919-53

Therapeutic area
Diseases [C] - Nervous System Diseases [C10]|

Investigated Disease
Primary Progressive Multiple Sclerosis (PPMS)

Scientific Title
A Phase III Multicenter, Randomized, Double-Blind, Double-Dummy, Parallel-Group Study to Evaluate the Efficacy and Safety of Fenebrutinib Compared with Ocrelizumab in Adult Patients with Primary Progressive Multiple Sclerosis

Rationale

Not provided

Main Objective

To evaluate the efficacy of fenebrutinib compared with ocrelizumab in patients with PPMS regardless of adherence to randomized treatment

Primary Endpoints

1. Time to onset of composite 12-week confirmed disability progression (cCDP12)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of fenebrutinib treatment compared with ocrelizumab
To evaluate the safety of fenebrutinib compared with ocrelizumab
To characterize the fenebrutinib PK profile

Secondary Endpoints

1. Time to onset of composite 24 week CDP (cCDP24)
2. Time to onset of 12-week CDP (CDP12)
3. Time to onset of 24 week CDP (CDP24)
4. Percent change in total brain volume from Week 24 as assessed by MRI scan
5. Percent change from screening to Week 120 in serum neurofilament light chain (NfL) levels
6. Change patient-reported physical impacts of MS (as measured by Multiple Sclerosis Impact Scale, 29-Item [MSIS-29] physical scale)
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13. Plasma concentration of fenebrutinib at specified timepoints

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Ability to comply with the study protocol
A diagnosis of PPMS in accordance to the revised 2017 McDonald Criteria
Disability progression in the 12 months prior to screening, as assessed by the Pre-Baseline Disability Progression Questionnaire
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History of cancer, including hematologic malignancy and solid tumors, within 10 years of screening
Immunocompromised state

Calendar

(Last Update: 21/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
21/01/2021	26/03/2021	19/04/2021	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
21/04/2023	Not aported	Not aported	Not aported	Not aported

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

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Sites

Closed (07/05/2021)

COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA

Coruña, A

CORUÑA

Active (26/03/2021)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

Vigo

PONTEVEDRA

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

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Neurología

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

Hospital Universitari Arnau De Vilanova De La Gerencia Territorial De Lleida

Lleida

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LÉRIDA

Active (04/08/2021)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

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

Hospital Universitario Puerta Del Mar

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Active (26/03/2021)

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Active (08/09/2021)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Medication

Fenebrutinib

FILM-COATED TABLET

ORAL

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Active Principles: N/A

Experimental

Ocrevus 300 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L04AA36 - OCRELIZUMAB

Active Principles: N/A

Experimental

Ocrevus 300 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L04AA36 - OCRELIZUMAB

Active Principles: N/A

Experimental

No results