A Study to Evaluate the Efficacy and Safety of Ocrelizumab in Adults with Primary Progressive Multiple Sclerosis

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	637
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2023-505980-36-00 (CTIS)

Cod. Protocolo
WA40404

Transicionado 2018-001511-73

Área terapéutica
·Enfermedades [C] - Sistema Nervioso [C10]
·Enfermedades [C] - Patologías del sistema inmunitario [C20]

Enfermedad investigada
Primary progressive multiple sclerosis (PPMS)

Título Científico
A Phase IIIb Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of ocrelizumab compared with placebo-in all randomized patients and in patients with MRI activity (MRI activity is defined as presence of T1 Gd+ lesion[s] and/or new and/or enlarging T2 lesion[s] as detected by MRI scans during the screening phase) on the basis of the following endpoint:Time to onset of composite 12-week CDP defined as the time from randomization to the first occurrence of at least one of the following progression events: 12-week CDP in 9-HPT, defined as a 20% worsening from baseline in 9-HPT confirmed for at least 12 weeks 12-week CDP in EDSS score, defined as an increase of 1.0 point from baseline EDSS score in patients with a baseline EDSS score 5.5 or an increase of 0.5 point in patients with a baseline EDSS score of > 5.5 that is confirmed for at least 12 weeks

Variables de Evaluación Primaria

1. Time to onset of composite 12-week CDP defined as the time from randomization to the first occurrence of either 12-week CDP in 9-HPT, or 12-week CDP in EDSS

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of ocrelizumab compared with placebo for all randomized patients on the basis of the endpoints below Time to 12-week CDP in 9-HPT Time to 12-week CDP in EDSS Time to 24-week CDP in 9-HPT Time to 24-week CDP in EDSS Annual rate of percent change from baseline in total volume of T2 lesions Annual rate of percent change from Week 24 in total brain volume
To evaluate the safety of ocrelizumab compared with placebo and over time for all patients by the proportion of patients with adverse events, laboratory abnormalities
To assess the immunogenicity, by the presence of anti-drug antibody to ocrelizumab during the study relative to baseline and the relationship to pharmacokinetics (PK), pharmacodynamics, efficacy and safety
To characterize the PK profile of the ocrelizumab and its PD, measured by blood B-cell levels

Variables de Evaluación Secundaria

1. Time to 12-week CDP in EDSS, as a pre-defined increase in EDSS score confirmed for at least 12 weeks
2. Time to 24-week CDP in 9-HPT
3. Time to 24-week CDP in EDSS, as a pre-defined increase in EDSS score confirmed for at least 24 weeks
4. Annual rate of percent change from baseline in total volume of T2 lesions
5. Annual rate of percent change from Week 24 in total brain volume
6. Incidence and nature of adverse events, serious adverse events, adverse events leading to study treatment

withdrawal
7. Change from baseline in laboratory test results for hematology and chemistry association of decrease in certain laboratory parameters, and serious infections
8. Presence of ADA during the study relative to baseline
9. Total plasma clearances (CL) of ocrelizumab
10. Volumes of distribution(Vd) of ocrelizumab
11. Area under the concentration-time curve (AUC) of ocrelizumab

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Diagnosis of PPMS in accordance with the McDonald criteria (Thompson et al. 2017) 2. EDSS score at screening and baseline 3.0 to 8.0, inclusive 3. Disease duration from the onset of multiple sclerosis (MS) symptoms relative to randomization date: o Less than 20 years in patients with an EDSS score at screening 7.0-8.0 o Less than 15 years in patients with an EDSS at screening 5.5-6.5 o Less than 10 years in patients with an EDSS at screening 5.0 4. Documented history or presence at screening of at least one of the following laboratory findings in a cerebrospinal fluid specimen o Elevated IgG index o One or more IgG oligoclonal bands detected by isoelectric focusing 5. Screening and baseline 9-HPT completed in > 25 seconds (average of the two hands) 6. Neurological stability for 30 days prior to baseline

Criterios de Exclusión

1. History of relapsing-remitting or secondary progressive MS at screening 2. Confirmed serious opportunistic infection 3. Patients who have or have had confirmed or a high degree of suspicion of progressive multifocal leukoencephalopathy 4. Known active malignancy or are being actively monitored for recurrence of malignancy 5. Immunocompromised state defined as one or more of the following: CD4 count < 250/L, absolute neutrophil count <1.5 x 103/L, Serum IgG < 4.6 g/L 6. Receipt of a live-attenuated vaccine within 6 weeks prior to randomization

Calendario

(Última actualización: 28/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
21/08/2019	19/09/2019	25/09/2019	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
18/09/2023	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 Parc Tauli

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ceic@tauli.cat

937458454-937458451

Centros

Activo (12/12/2019)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Neurología

Activo (16/10/2019)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

Vigo

PONTEVEDRA

Neurología

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

Complexo Hospitalario Universitario De Vigo

Vigo

PONTEVEDRA

Servicio de neurología

Cerrado (24/07/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

Neurología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de neurología

Cerrado (23/07/2026)

HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Neurología

Cerrado (29/01/2021)

HOSPITAL GENERAL UNIVERSITARIO DE CASTELLON

Castellón de la Plana/Castelló de la Plana

CASTELLÓN

Neurología

Activo (10/10/2019)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Neurología

Activo (16/12/2019)

HOSPITAL RAMÓN Y CAJAL

Madrid

MADRID

Neurología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de neurología

Activo (18/09/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Centro de Esclerosis Multiple de Catalunya (Cemcat)

Cerrado (13/03/2024)

HOSPITAL UNIVERSITARIO DE CRUCES

Barakaldo

VIZCAYA/BIZKAIA

Neurología

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de neurología

Cerrado (12/03/2024)

HOSPITAL UNIVERSITARIO MADRID SANCHINARRO

Madrid

MADRID

Neurología

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Servicio de neurología

Activo (16/01/2020)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Neurología

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Servicio de neurología

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Servicio de neurología

Cerrado (24/10/2023)

HOSPITAL UNIVERSITARIO REGIONAL DE MÁLAGA

Málaga

MÁLAGA

Servicio de Neurología

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Servicio de neurología

Activo (18/10/2019)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Neurología

Activo (05/11/2019)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Neurología

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Servicio de neurología

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Servicio de neurología

Medicamentos

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

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

Experimental

DIPHENHYDRAMINE HYDROCHLORIDE
TABLET
ORAL

-
Principios Activos: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

-
Principios Activos: N/A

Experimental

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

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

Experimental

Dormutil N
TABLET
ORAL

Código ATC: N05CM - OTROS HIPNOTICOS Y SEDANTES
Principios Activos: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

-
-
INTRAVENIOUS INFUSION

Código ATC: H02AB04 - METILPREDNISOLONA
Principios Activos: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Ocrelizumab in Adults with Primary Progressive Multiple Sclerosis

State	Type of participants	Age Ranges
End of recruitment	Not provided	Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	637
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2023-505980-36-00 (CTIS)

Protocol Code
WA40404

Transitioned 2018-001511-73

Therapeutic area
·Diseases [C] - Nervous System Diseases [C10]
·Diseases [C] - Immune System Diseases [C20]

Investigated Disease
Primary progressive multiple sclerosis (PPMS)

Scientific Title
A Phase IIIb Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Ocrelizumab in Adults With Primary Progressive Multiple Sclerosis

Rationale

Not provided

Main Objective

To evaluate the efficacy of ocrelizumab compared with placebo-in all randomized patients and in patients with MRI activity (MRI activity is defined as presence of T1 Gd+ lesion[s] and/or new and/or enlarging T2 lesion[s] as detected by MRI scans during the screening phase) on the basis of the following endpoint:Time to onset of composite 12-week CDP defined as the time from randomization to the first occurrence of at least one of the following progression events: 12-week CDP in 9-HPT, defined as a 20% worsening from baseline in 9-HPT confirmed for at least 12 weeks 12-week CDP in EDSS score, defined as an increase of 1.0 point from baseline EDSS score in patients with a baseline EDSS score 5.5 or an increase of 0.5 point in patients with a baseline EDSS score of > 5.5 that is confirmed for at least 12 weeks

Primary Endpoints

1. Time to onset of composite 12-week CDP defined as the time from randomization to the first occurrence of either 12-week CDP in 9-HPT, or 12-week CDP in EDSS

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of ocrelizumab compared with placebo for all randomized patients on the basis of the endpoints below Time to 12-week CDP in 9-HPT Time to 12-week CDP in EDSS Time to 24-week CDP in 9-HPT Time to 24-week CDP in EDSS Annual rate of percent change from baseline in total volume of T2 lesions Annual rate of percent change from Week 24 in total brain volume
To evaluate the safety of ocrelizumab compared with placebo and over time for all patients by the proportion of patients with adverse events, laboratory abnormalities
To assess the immunogenicity, by the presence of anti-drug antibody to ocrelizumab during the study relative to baseline and the relationship to pharmacokinetics (PK), pharmacodynamics, efficacy and safety
To characterize the PK profile of the ocrelizumab and its PD, measured by blood B-cell levels

Secondary Endpoints

1. Time to 12-week CDP in EDSS, as a pre-defined increase in EDSS score confirmed for at least 12 weeks
2. Time to 24-week CDP in 9-HPT
3. Time to 24-week CDP in EDSS, as a pre-defined increase in EDSS score confirmed for at least 24 weeks
4. Annual rate of percent change from baseline in total volume of T2 lesions
5. Annual rate of percent change from Week 24 in total brain volume
6. Incidence and nature of adverse events, serious adverse events, adverse events leading to study treatment

withdrawal
7. Change from baseline in laboratory test results for hematology and chemistry association of decrease in certain laboratory parameters, and serious infections
8. Presence of ADA during the study relative to baseline
9. Total plasma clearances (CL) of ocrelizumab
10. Volumes of distribution(Vd) of ocrelizumab
11. Area under the concentration-time curve (AUC) of ocrelizumab

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Diagnosis of PPMS in accordance with the McDonald criteria (Thompson et al. 2017) 2. EDSS score at screening and baseline 3.0 to 8.0, inclusive 3. Disease duration from the onset of multiple sclerosis (MS) symptoms relative to randomization date: o Less than 20 years in patients with an EDSS score at screening 7.0-8.0 o Less than 15 years in patients with an EDSS at screening 5.5-6.5 o Less than 10 years in patients with an EDSS at screening 5.0 4. Documented history or presence at screening of at least one of the following laboratory findings in a cerebrospinal fluid specimen o Elevated IgG index o One or more IgG oligoclonal bands detected by isoelectric focusing 5. Screening and baseline 9-HPT completed in > 25 seconds (average of the two hands) 6. Neurological stability for 30 days prior to baseline

Exclusion criteria

1. History of relapsing-remitting or secondary progressive MS at screening 2. Confirmed serious opportunistic infection 3. Patients who have or have had confirmed or a high degree of suspicion of progressive multifocal leukoencephalopathy 4. Known active malignancy or are being actively monitored for recurrence of malignancy 5. Immunocompromised state defined as one or more of the following: CD4 count < 250/L, absolute neutrophil count <1.5 x 103/L, Serum IgG < 4.6 g/L 6. Receipt of a live-attenuated vaccine within 6 weeks prior to randomization

Calendar

(Last Update: 28/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
21/08/2019	19/09/2019	25/09/2019	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
18/09/2023	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

CEIm Parc Tauli

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Sites

Active (12/12/2019)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Neurología

Active (16/10/2019)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE VIGO

Vigo

PONTEVEDRA

Neurología

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

Complexo Hospitalario Universitario De Vigo

Vigo

PONTEVEDRA

Servicio de neurología

Closed (24/07/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

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Neurología

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

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Málaga

MÁLAGA

Servicio de Neurología

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

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SEVILLA

Servicio de neurología

Active (18/10/2019)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Neurología

Active (05/11/2019)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Neurología

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Servicio de neurología

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Servicio de neurología

Medication

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

ATC code: L04AA36 - OCRELIZUMAB
Active Principles: N/A

Experimental

DIPHENHYDRAMINE HYDROCHLORIDE
TABLET
ORAL

-
Active Principles: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

-
Active Principles: N/A

Experimental

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

ATC code: L04AA36 - OCRELIZUMAB
Active Principles: N/A

Experimental

Dormutil N
TABLET
ORAL

ATC code: N05CM - OTROS HIPNOTICOS Y SEDANTES
Active Principles: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-
Active Principles: N/A

Experimental

-
-
INTRAVENIOUS INFUSION

ATC code: H02AB04 - METILPREDNISOLONA
Active Principles: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-
Active Principles: N/A

Experimental

METHYLPREDNISOLONE SODIUM SUCCINATE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

No results