A Study to Evaluate the Efficacy and Safety of Polatuzumab Vedotin in Combination with Rituximab and CHP (R-CHP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with Diffuse Large B-Cell Lymphoma

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	644
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
2024-516904-40-00 (CTIS)

Cod. Protocolo
GO39942

Transicionado 2017-002023-21

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Previously Untreated Diffuse large B-cell lymphoma (DLBCL)

Título Científico
A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL COMPARING THE EFFICACY AND SAFETY OF POLATUZUMAB VEDOTIN IN COMBINATION WITH RITUXIMAB AND CHP (R-

CHP) VERSUS RITUXIMAB AND CHOP (R-CHOP) IN PREVIOUSLY UNTREATED PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of polatuzumab vedotin plus rituximab plus cyclophosphamide, doxorubicin, and prednisone (R-CHP) compared with rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) with respect to progression-free survival (PFS)

Variables de Evaluación Primaria

1. Progression-free survival, defined as the time from randomization to the first occurrence of disease progression or relapse as assessed by the investigator by using the Lugano Response Criteria for Malignant Lymphoma, or death from any cause, whichever occurs earlier

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of polatuzumab vedotin plus R-CHP compared with R-CHOP with respect to secondary efficacy endpoints
To evaluate the safety of polatuzumab vedotin plus R-CHP compared with R-CHOP
To characterize the pharmacokinetics of polatuzumab vedotin
To evaluate the immune response to polatuzumab vedotin

Variables de Evaluación Secundaria

1. Event-free survival (efficacy) as determined by the investigator
2. Complete response rate at end of treatment by fluorodeoxyglucose positron emission tomography (FDG-PET) as determined by blinded independent central review (BICR)
3. Overall Survival (OS)
4. CR rate at end of treatmentby FDG-PET as determined by the investigator
5. 2-year progression-free survival rate (PFS24) as determined by the investigator
6. Disease-free survival (DFS)
7. Duration of response (DOR)
8. Event-free survival (all causes)
9. Time to deterioration in european organisation for research and treatment of cancer quality of life-core 30

questionnaire (EORTC QLQ-C30) physical functioning and fatigue and functional assessment of cancer therapy-lymphoma lymphoma subscale (FACT-Lym LymS)
10. Proportion of patients achieving meaningful improvement in EORTC QLQ-C30 physical functioning and fatigue, and FACT-Lym LymS
11. EORTC QLQ-C30 rate of treatment-related symptoms and Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Neurotoxicity (FACT/GOG-NTX) peripheral neuropathy rate
12. Incidence, nature, and severity of adverse events, with severity determined through use of national cancer institute common terminology criteria for adverse events, version 4.0 (NCI CTCAE v4.0)
13. Incidence of peripheral neuropathy rates and severity determined through use of NCI CTCAE v4.0
14. Incidence and nature of study drug discontinuation, dose reduction, and dose delay due to adverse events
15. Dose intensities of study drugs
16. Plasma and/or serum concentration of polatuzumab vedotin related analytes at specified time points
17. Incidence of anti-drug antibodies (ADAs) to polatuzumab vedotin during the study relative to the prevalence of ADAs to polatuzumab vedotin at baseline

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Previously untreated patients with CD20-positive DLBCL, including one of the following diagnoses by 2016 WHO classification of lymphoid neoplasms: DLBCL, not otherwise specified (NOS) including germinal center B-cell type, activated B-cell type T-cell/histiocyte-rich large B-cell lymphoma Epstein-Barr virus-positive DLBCL, NOS ALK-positive large B-cell lymphoma HHV8-positive DLBCL, NOS High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements (double-hit or triple-hit lymphoma) High-grade B-cell lymphoma, NOS International Prognostic Index (IPI) score of 2-5 Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 Life expectancy 12 months At least one bi-dimensionally measurable lesion, defined as >1.5 cm in its longest dimension as measured by computed tomography (CT) or magnetic resonance imaging (MRI) Left ventricular ejection fraction (LVEF) 50% on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)

Criterios de Exclusión

Prior organ transplantation Current Grade >1 peripheral neuropathy by clinical examination or demyelinating form of Charcot-Marie-Tooth disease History of indolent lymphoma Prior treatment with cytotoxic drugs within 5 years of screening for any condition (e.g., cancer, rheumatoid arthritis) or prior use of any anti-CD20 antibody Prior use of any monoclonal antibody within 3 months of the start of Cycle 1; any investigational therapy within 28 days prior to the start of Cycle 1; vaccination with live vaccines within 28 days prior the start of Cycle 1 Prior radiotherapy to the mediastinal/pericardial region

Calendario

(Última actualización: 23/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
29/01/2018	27/03/2018	26/04/2018	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
28/06/2019	No aportado	No aportado	30/04/2026	07/05/2026

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 Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

Cerrado (12/06/2025)

COMPLEJO HOSPITALARIO DE ESPECIALIDADES VIRGEN DE LA VICTORIA

Málaga

Cerrado (02/07/2026)

COMPLEJO HOSPITALARIO DE NAVARRA

Pamplona/Iruña

NAVARRA

Cerrado (16/07/2026)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Cerrado (06/07/2026)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Cerrado (17/06/2026)

Hospital Clínic de Barcelona

Barcelona

BARCELONA

Cerrado (14/07/2026)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology Service

Cerrado (14/07/2026)

Hospital de la Santa Creu i Sant Pau

Barcelona

BARCELONA

Cerrado (14/07/2026)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Cerrado (02/06/2026)

HOSPITAL SAN PEDRO DE ALCÁNTARA

Cáceres

CÁCERES

Cerrado (02/06/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology and Hemotherapy Service

Cerrado (19/02/2026)

Hospital Universitari de Girona Dr. Josep Trueta

Girona

Cerrado (30/10/2025)

Hospital Universitari Vall d'Hebron

Barcelona

BARCELONA

Cerrado (15/07/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Cerrado (02/07/2026)

Hospital Universitario La Paz

Madrid

MADRID

Hematology Service

Cerrado (30/08/2019)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

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

Institut Catala D'oncologia

Girona

GERONA

Hematology Service

Cerrado (18/06/2026)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology and Hemotherapy Service

Cerrado (18/06/2026)

Institut Catala D'oncologia

Girona

GERONA

Hematology Service

Cerrado (18/06/2026)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medicamentos

-
-
INTRAVENOUS USE

Código ATC: L01CA02 - VINCRISTINA
Principios Activos: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Polivy 140 mg powder for concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01FX14 - POLATUZUMAB VEDOTINA
Principios Activos: N/A

Huérfano
Experimental

Sin resultados

A Study to Evaluate the Efficacy and Safety of Polatuzumab Vedotin in Combination with Rituximab and CHP (R-CHP) Versus Rituximab and CHOP (R-CHOP) in Previously Untreated Patients with Diffuse Large B-Cell Lymphoma

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	644
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
2024-516904-40-00 (CTIS)

Protocol Code
GO39942

Transitioned 2017-002023-21

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Previously Untreated Diffuse large B-cell lymphoma (DLBCL)

Scientific Title
A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL COMPARING THE EFFICACY AND SAFETY OF POLATUZUMAB VEDOTIN IN COMBINATION WITH RITUXIMAB AND CHP (R-

CHP) VERSUS RITUXIMAB AND CHOP (R-CHOP) IN PREVIOUSLY UNTREATED PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA

Rationale

Not provided

Main Objective

To evaluate the efficacy of polatuzumab vedotin plus rituximab plus cyclophosphamide, doxorubicin, and prednisone (R-CHP) compared with rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP) with respect to progression-free survival (PFS)

Primary Endpoints

1. Progression-free survival, defined as the time from randomization to the first occurrence of disease progression or relapse as assessed by the investigator by using the Lugano Response Criteria for Malignant Lymphoma, or death from any cause, whichever occurs earlier

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of polatuzumab vedotin plus R-CHP compared with R-CHOP with respect to secondary efficacy endpoints
To evaluate the safety of polatuzumab vedotin plus R-CHP compared with R-CHOP
To characterize the pharmacokinetics of polatuzumab vedotin
To evaluate the immune response to polatuzumab vedotin

Secondary Endpoints

1. Event-free survival (efficacy) as determined by the investigator
2. Complete response rate at end of treatment by fluorodeoxyglucose positron emission tomography (FDG-PET) as determined by blinded independent central review (BICR)
3. Overall Survival (OS)
4. CR rate at end of treatmentby FDG-PET as determined by the investigator
5. 2-year progression-free survival rate (PFS24) as determined by the investigator
6. Disease-free survival (DFS)
7. Duration of response (DOR)
8. Event-free survival (all causes)
9. Time to deterioration in european organisation for research and treatment of cancer quality of life-core 30

questionnaire (EORTC QLQ-C30) physical functioning and fatigue and functional assessment of cancer therapy-lymphoma lymphoma subscale (FACT-Lym LymS)
10. Proportion of patients achieving meaningful improvement in EORTC QLQ-C30 physical functioning and fatigue, and FACT-Lym LymS
11. EORTC QLQ-C30 rate of treatment-related symptoms and Functional Assessment of Cancer Therapy/Gynecologic Oncology Group Neurotoxicity (FACT/GOG-NTX) peripheral neuropathy rate
12. Incidence, nature, and severity of adverse events, with severity determined through use of national cancer institute common terminology criteria for adverse events, version 4.0 (NCI CTCAE v4.0)
13. Incidence of peripheral neuropathy rates and severity determined through use of NCI CTCAE v4.0
14. Incidence and nature of study drug discontinuation, dose reduction, and dose delay due to adverse events
15. Dose intensities of study drugs
16. Plasma and/or serum concentration of polatuzumab vedotin related analytes at specified time points
17. Incidence of anti-drug antibodies (ADAs) to polatuzumab vedotin during the study relative to the prevalence of ADAs to polatuzumab vedotin at baseline

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Previously untreated patients with CD20-positive DLBCL, including one of the following diagnoses by 2016 WHO classification of lymphoid neoplasms: DLBCL, not otherwise specified (NOS) including germinal center B-cell type, activated B-cell type T-cell/histiocyte-rich large B-cell lymphoma Epstein-Barr virus-positive DLBCL, NOS ALK-positive large B-cell lymphoma HHV8-positive DLBCL, NOS High-grade B-cell lymphoma with MYC and BCL2 and/or BCL6 rearrangements (double-hit or triple-hit lymphoma) High-grade B-cell lymphoma, NOS International Prognostic Index (IPI) score of 2-5 Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2 Life expectancy 12 months At least one bi-dimensionally measurable lesion, defined as >1.5 cm in its longest dimension as measured by computed tomography (CT) or magnetic resonance imaging (MRI) Left ventricular ejection fraction (LVEF) 50% on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)

Exclusion criteria

Prior organ transplantation Current Grade >1 peripheral neuropathy by clinical examination or demyelinating form of Charcot-Marie-Tooth disease History of indolent lymphoma Prior treatment with cytotoxic drugs within 5 years of screening for any condition (e.g., cancer, rheumatoid arthritis) or prior use of any anti-CD20 antibody Prior use of any monoclonal antibody within 3 months of the start of Cycle 1; any investigational therapy within 28 days prior to the start of Cycle 1; vaccination with live vaccines within 28 days prior the start of Cycle 1 Prior radiotherapy to the mediastinal/pericardial region

Calendar

(Last Update: 23/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
29/01/2018	27/03/2018	26/04/2018	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
28/06/2019	Not aported	Not aported	30/04/2026	07/05/2026

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 Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Sites

Closed (12/06/2025)

COMPLEJO HOSPITALARIO DE ESPECIALIDADES VIRGEN DE LA VICTORIA

Málaga

Closed (02/07/2026)

COMPLEJO HOSPITALARIO DE NAVARRA

Pamplona/Iruña

NAVARRA

Closed (16/07/2026)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Closed (06/07/2026)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Closed (17/06/2026)

Hospital Clínic de Barcelona

Barcelona

BARCELONA

Closed (14/07/2026)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology Service

Closed (14/07/2026)

Hospital de la Santa Creu i Sant Pau

Barcelona

BARCELONA

Closed (14/07/2026)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Closed (02/06/2026)

HOSPITAL SAN PEDRO DE ALCÁNTARA

Cáceres

CÁCERES

Closed (02/06/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology and Hemotherapy Service

Closed (19/02/2026)

Hospital Universitari de Girona Dr. Josep Trueta

Girona

Closed (30/10/2025)

Hospital Universitari Vall d'Hebron

Barcelona

BARCELONA

Closed (15/07/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Closed (02/07/2026)

Hospital Universitario La Paz

Madrid

MADRID

Hematology Service

Closed (30/08/2019)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

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

Institut Catala D'oncologia

Girona

GERONA

Hematology Service

Closed (18/06/2026)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology and Hemotherapy Service

Closed (18/06/2026)

Institut Catala D'oncologia

Girona

GERONA

Hematology Service

Closed (18/06/2026)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medication

-

-

INTRAVENOUS USE

ATC code: L01CA02 - VINCRISTINA

Active Principles: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

Polivy 140 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENOUS USE

ATC code: L01FX14 - POLATUZUMAB VEDOTINA

Active Principles: N/A

Orphan **Experimental**

No results