A Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination with Rituximab Plus Gemcitabine Plus Oxaliplatin (R- GEMOX) Versus R- GEMOX Alone in Patients with Relapsed/Refractory 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	284
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia	NO

Información

Identificador
2024-512537-33-00 (CTIS)

Cod. Protocolo
MO40598

Transicionado 2018-003727-10

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

Enfermedad investigada
Relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

Título Científico
A Phase III, Open-Label, Multicenter, Randomized Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination with Rituximab Plus Gemcitabine Plus Oxaliplatin (R- GEMOX) Versus R- GEMOX Alone in Patients

with Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of Pola-R-GemOx compared with R-GemOx alone on basis of the overall survival (OS) (Stage 2) To evaluate the safety and tolerability of Polatuzumab Vedotin (Pola)-R-GemOx as a combination therapy on basis of incidence, nature and severity of physical findings and adverse events (AEs), with a specific focus on peripheral neuropathy (PN), according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5 (NCI CTCAE v5.0) (Stage 1)

Variables de Evaluación Primaria

1. Incidence, nature and severity of physical findings and AEs, with a specific focus on peripheral neuropathy, according to the NCI CTCAE v5.0 (Stage 1)
2. Overall survival (Stage 2)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate safety and tolerability of Pola-R-GemOx as a combination therapy compared to R-GemOx, on the basis of incidence and assessment of peripheral neuropathy, tolerability, prevalence of anti-drug antibodies (ADA), incidence/nature/severity of AEs (Stage 1, 2)
To evaluate efficacy of Pola-R-GemOx compared to R-GemOx alone, on the basis of complete response (CR), objective response rate (ORR), best overall response (BOR), progression-free survival (PFS), event-free survival (EFS) (Stage 1, 2), OS (Pola-R-GemOx)- (Stage 1), duration of OR (DOR) (Stage 2)
To evaluate immunogenicity of polatuzumab vedotin, on the basis of prevalence of ADAs (Stage 1, 2)
To evaluate the impact of treatment, disease on aspects of health-related quality of life (Stage 2)

Variables de Evaluación Secundaria

1. Incidence and assessment of peripheral neuropathy, as measured by Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity 12-Item Scale (FACT-/GOG-NTX-12) (Stage 1)
2. Incidence, nature and severity of AEs (including peripheral neuropathy) according to NCI CTCAE v5.0 and physical findings (Stage 2)
3. Tolerability, as measured by dose interruptions, dose reductions and dose intensity (Stage 1 and 2)
4. Prevalence of ADAs to polatuzumab vedotin at baseline and incidence of ADAs during the study (Stage 1 and 2)

5. CR as determined by an independent review committee (IRC) (Stage 2)
6. CR as determined by investigator (Stage 1 and 2)
7. ORR as determined by an IRC (Stage 2)
8. ORR as determined by investigator (Stage 1 and 2)
9. BOR as determined by investigator (Stage 1 and 2)
10. PFS as determined by investigator (Stage 1 and 2)
11. OS (Stage 1)
12. Event-free survival (EFSeff) as determined by investigator (Stage 1 and 2)
13. DOR as determined by investigator (Stage 2)
14. Time to deterioration in physical functioning and fatigue as measured by the European Organisation for the Research and Treatment of Cancer Quality-of-Life Questionnaire, Core 30 (Stage 2)
15. Time to progression in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy-Lymphoma subscale (Stage 2)
16. Change from baseline in peripheral neuropathy as measured by the FACT/GOG-NTX-12 subscale score (Stage 2)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Histologically-confirmed DLBCL, not otherwise specified or history of transformation of indolent disease to DLBCL Relapsed or refractory disease At least one (>= 1) line of prior systemic therapy At least one bi-dimensionally measurable lesion Eastern Cooperative Oncology Group performance status of 0, 1 or 2 Adequate hematological function

Criterios de Exclusión

History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products Contraindication to rituximab, gemcitabine or oxaliplatin Peripheral neuropathy assessed to be > Grade 1 according to NCI CTCAE v5.0 at enrollment Prior use of polatuzumab vedotin or a gemcitabine + platinum-based agent combination Enrollment in any previous or ongoing polatuzumab vedotin trial Treatment with radiotherapy, chemotherapy, immunotherapy, immunosuppressive therapy, or any investigational agent for the purposes of treating cancer within 2 weeks prior to Cycle 1 Day 1

Calendario

(Última actualización: 03/06/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
16/12/2019	19/12/2019	06/03/2024	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
23/05/2023	No aportado	No aportado	29/11/2024	30/11/2024

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

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Centros

Cerrado (11/04/2025)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Hematología

Cerrado (22/04/2025)

COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS

San Cristóbal de La Laguna

STA. CRUZ DE TENERIFE

Hematología

Cerrado (16/04/2025)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Hematología

Cerrado (15/04/2025)

HOSPITAL UNIVERSITARIO DR. PESET ALEIXANDRE

Valencia

VALENCIA

Hematología

Cerrado (31/03/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

Medicamentos

-
-
INTRAVENOUS USE

Código ATC: L01BC05 - GEMCITABINA
Principios Activos: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01XC02 - 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

-
-
INTRAVENOUS USE

Código ATC: L01XA03 - OXALIPLATINO
Principios Activos: N/A

Experimental

Sin resultados

A Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination with Rituximab Plus Gemcitabine Plus Oxaliplatin (R- GEMOX) Versus R- GEMOX Alone in Patients with Relapsed/Refractory 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	284
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
2024-512537-33-00 (CTIS)

Protocol Code
MO40598

Transitioned 2018-003727-10

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

Investigated Disease
Relapsed/refractory diffuse large B-cell lymphoma (DLBCL)

Scientific Title
A Phase III, Open-Label, Multicenter, Randomized Study Evaluating the Safety and Efficacy of Polatuzumab Vedotin in Combination with Rituximab Plus Gemcitabine Plus Oxaliplatin (R- GEMOX) Versus R- GEMOX Alone in Patients

with Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Rationale

Not provided

Main Objective

To evaluate the efficacy of Pola-R-GemOx compared with R-GemOx alone on basis of the overall survival (OS) (Stage 2) To evaluate the safety and tolerability of Polatuzumab Vedotin (Pola)-R-GemOx as a combination therapy on basis of incidence, nature and severity of physical findings and adverse events (AEs), with a specific focus on peripheral neuropathy (PN), according to the National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5 (NCI CTCAE v5.0) (Stage 1)

Primary Endpoints

1. Incidence, nature and severity of physical findings and AEs, with a specific focus on peripheral neuropathy, according to the NCI CTCAE v5.0 (Stage 1)
2. Overall survival (Stage 2)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate safety and tolerability of Pola-R-GemOx as a combination therapy compared to R-GemOx, on the basis of incidence and assessment of peripheral neuropathy, tolerability, prevalence of anti-drug antibodies (ADA), incidence/nature/severity of AEs (Stage 1, 2)
To evaluate efficacy of Pola-R-GemOx compared to R-GemOx alone, on the basis of complete response (CR), objective response rate (ORR), best overall response (BOR), progression-free survival (PFS), event-free survival (EFS) (Stage 1, 2), OS (Pola-R-GemOx)- (Stage 1), duration of OR (DOR) (Stage 2)
To evaluate immunogenicity of polatuzumab vedotin, on the basis of prevalence of ADAs (Stage 1, 2)
To evaluate the impact of treatment, disease on aspects of health-related quality of life (Stage 2)

Secondary Endpoints

1. Incidence and assessment of peripheral neuropathy, as measured by Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity 12-Item Scale (FACT-/GOG-NTX-12) (Stage 1)
2. Incidence, nature and severity of AEs (including peripheral neuropathy) according to NCI CTCAE v5.0 and physical findings (Stage 2)
3. Tolerability, as measured by dose interruptions, dose reductions and dose intensity (Stage 1 and 2)
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5. CR as determined by an independent review committee (IRC) (Stage 2)
6. CR as determined by investigator (Stage 1 and 2)
7. ORR as determined by an IRC (Stage 2)
8. ORR as determined by investigator (Stage 1 and 2)
9. BOR as determined by investigator (Stage 1 and 2)
10. PFS as determined by investigator (Stage 1 and 2)
11. OS (Stage 1)
12. Event-free survival (EFSeff) as determined by investigator (Stage 1 and 2)
13. DOR as determined by investigator (Stage 2)
14. Time to deterioration in physical functioning and fatigue as measured by the European Organisation for the Research and Treatment of Cancer Quality-of-Life Questionnaire, Core 30 (Stage 2)
15. Time to progression in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy-Lymphoma subscale (Stage 2)
16. Change from baseline in peripheral neuropathy as measured by the FACT/GOG-NTX-12 subscale score (Stage 2)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Histologically-confirmed DLBCL, not otherwise specified or history of transformation of indolent disease to DLBCL Relapsed or refractory disease At least one (>= 1) line of prior systemic therapy At least one bi-dimensionally measurable lesion Eastern Cooperative Oncology Group performance status of 0, 1 or 2 Adequate hematological function

Exclusion criteria

History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies (or recombinant antibody-related fusion proteins) or known sensitivity or allergy to murine products Contraindication to rituximab, gemcitabine or oxaliplatin Peripheral neuropathy assessed to be > Grade 1 according to NCI CTCAE v5.0 at enrollment Prior use of polatuzumab vedotin or a gemcitabine + platinum-based agent combination Enrollment in any previous or ongoing polatuzumab vedotin trial Treatment with radiotherapy, chemotherapy, immunotherapy, immunosuppressive therapy, or any investigational agent for the purposes of treating cancer within 2 weeks prior to Cycle 1 Day 1

Calendar

(Last Update: 03/06/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
16/12/2019	19/12/2019	06/03/2024	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
23/05/2023	Not aported	Not aported	29/11/2024	30/11/2024

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

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CEIm Hospital Universitario 12 de Octubre

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Sites

Closed (11/04/2025)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Hematología

Closed (22/04/2025)

COMPLEJO HOSPITALARIO UNIVERSITARIO DE CANARIAS

San Cristóbal de La Laguna

STA. CRUZ DE TENERIFE

Hematología

Closed (16/04/2025)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Hematología

Closed (15/04/2025)

HOSPITAL UNIVERSITARIO DR. PESET ALEIXANDRE

Valencia

VALENCIA

Hematología

Closed (31/03/2025)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

Medication

-
-
INTRAVENOUS USE

ATC code: L01BC05 - GEMCITABINA
Active Principles: N/A

Experimental

MabThera 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: L01XC02 - 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

-
-
INTRAVENOUS USE

ATC code: L01XA03 - OXALIPLATINO
Active Principles: N/A

Experimental

No results