

This study is to find out the safety and effectiveness of Epcoritamab together with R-CHOP (rituximab, cyclophosphamide, doxorubicin HCL, vincristine, and prednisone) compared to only R-CHOP in subjects with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

Estado Fin Reclutamiento	Tipo de Participantes No aportado	Rangos de Edad Mayores de 64 , Adultos (18-64 años)
Género Ambos	Fases Fase III	Participantes esperados 542
Resultados Sin resultados	Bajo nivel intervención No	Enfermedad rara Si
Cobertura geográfica Sin determinar	Ámbitos del ensayo seguridad, eficacia	Terapia avanzada NO

Información

Identificador
2023-505277-32-00 (CTIS)

Cod. Protocolo
M20-621

Transicionado 2021-000168-31

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Diffuse Large B-Cell Lymphoma (DLBCL)

Título Científico
A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

(EPCORE DLBCL-2)

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to evaluate whether the addition of epcoritamab to 6 cycles of standard R-CHOP followed by 2 cycles of epcoritamab can prolong progression-free survival (PFS) compared with 6 cycles of standard R-CHOP alone followed by 2 cycles of rituximab in subjects with newly diagnosed DLBCL with an IPI of 3-5.

Variables de Evaluación Primaria

The primary endpoint is PFS defined as the duration from the date of randomization to the date of any of the following (whichever occurs first). The primary analysis population is the subset of subjects with an IPI of 3-5
Death due to any causes.
Disease progression based on the independent review committee (IRC) assessment per Lugano criteria.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The first secondary objective is to evaluate and compare PFS between the two treatment arms in subjects with newly diagnosed DLBCL with an IPI of 2-5 (i.e., all randomized subjects). The other secondary objectives are to evaluate and compare each key secondary endpoint for both the subset of subjects with an IPI of 3-5 and all randomized subjects per the hierarchical order specified in protocol Section 7.7.

Variables de Evaluación Secundaria

PFS in all randomized subjects.
CR on or after the EOT based on the IRC assessment per Lugano criteria, where EOT is defined as treatment completion or early treatment discontinuation.
OS, defined as time from randomization until death due to any causes.
MRD negativity.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years old and < 80 years old, with a life expectancy of 12 months. Subject is planned to receive treatment with 6 cycles of standard R CHOP per investigator determination. Subject must have an IPI score of 2-5. The number of subjects with an IPI 2 of will not exceed approximately 30% of the overall sample size.

Criterios de Exclusión

Subject with history of prior systemic anti-lymphoma therapy for DLBCL (including any definitive radiotherapy with curative intent) other than corticosteroids with or without vincristine during pre-phase treatment, or non-curative intent palliative radiotherapy with the stipulation that radiated lesions cannot be selected as target lesion for response assessment. Subject has clinically significant cardiovascular disease, including: Myocardial infarction or stroke within 6 months prior to enrollment. OR The following conditions within 3 months prior to enrollment: unstable or uncontrolled disease/condition related to or affecting cardiac function (e.g., unstable angina, congestive heart failure, New York Heart Association Class III IV), uncontrolled cardiac arrhythmia OR Screening 12-lead electrocardiogram showing a baseline QT interval as corrected by Fridericia's formula > 470 msec (male) or > 480 msec (female) OR Other clinically significant ECG abnormalities within 6 months prior to enrollment unless deemed stable and appropriately treated.

Calendario

(Última actualización: 01/06/2026)

Autorización 15/12/2022	Inicio de Ensayo 26/01/2023	Inclusión Primer Paciente 08/02/2023	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento 15/05/2024	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado
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Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinial Trial Helpdesk

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Provincial de Sevilla

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955043127

Centros

Activo (07/03/2023)	CLINICA UNIVERSIDAD DE NAVARRA Pamplona/Iruña NAVARRA Servicio de Hematología
Activo (06/02/2023)	Clinica Universidad De Navarra Madrid MADRID N/A
Cerrado (21/10/2024)	Hospital Clinic De Barcelona Barcelona BARCELONA Servicio de Hematología
Activo (04/04/2023)	HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA València VALENCIA Servicio de Hematología
Activo (04/03/2024)	Hospital Clínico Universitario Virgen De La Arrixaca Murcia MURCIA Onco Hematología
Activo (26/01/2023)	HOSPITAL DE LA SANTA CREU I SANT PAU Barcelona BARCELONA Servicio de Hematología
Activo (25/05/2023)	HOSPITAL DEL MAR. Barcelona BARCELONA Servicio de Hematología
Activo (13/09/2023)	HOSPITAL MD ANDERSON CANCER CENTER MADRID Madrid MADRID Servicio de Hematología

Activo (13/06/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

Activo (26/06/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Activo (21/02/2023)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Servicio de Hematología

Activo (02/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Servicio de Hematología

Activo (23/02/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Servicio de Hematología

Activo (08/03/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D''oncologia

Badalona

BARCELONA

N/A

Activo (19/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Activo (20/11/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medicamentos

Cyclophosphamide Injection 500 mg.

SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

Código ATC: L01AA01 - CICLOFOSFAMIDA

Principios Activos: N/A

Experimental

Vincristine Sulfate 1 mg/ml solution for injection

SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

Código ATC: L01CA02 - VINCRISTINA

Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Truxima 100 mg concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB

Principios Activos: N/A

Experimental

Truxima 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

Código ATC: L01FA01 - RITUXIMAB

Principios Activos: N/A

Experimental

Doxorubicinhydrochlorid Bendalis 2 mg/ml Injektionslösung

SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

Código ATC: L01DB01 - DOXORUBICINA

Principios Activos: N/A

Experimental

Prednisone Zentiva 5 mg compresse

TABLET
ORAL

Código ATC: H02AB07 - PREDNISONA

Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

This study is to find out the safety and effectiveness of Epcoritamab together with R-CHOP (rituximab, cyclophosphamide, doxorubicin HCL, vincristine, and prednisone) compared to only R-CHOP in subjects with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

State
End of recruitment

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase III

Expected Participants
542

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness

Advanced therapy
NO

Information

Identifier
2023-505277-32-00 (CTIS)

Protocol Code
M20-621

Transitioned 2021-000168-31

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Diffuse Large B-Cell Lymphoma (DLBCL)

Scientific Title
A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

(EPCORE DLBCL-2)

Rationale

Not provided

Main Objective

The primary objective of this study is to evaluate whether the addition of epcoritamab to 6 cycles of standard R-CHOP followed by 2 cycles of epcoritamab can prolong progression-free survival (PFS) compared with 6 cycles of standard R-CHOP alone followed by 2 cycles of rituximab in subjects with newly diagnosed DLBCL with an IPI of 3-5.

Primary Endpoints

The primary endpoint is PFS defined as the duration from the date of randomization to the date of any of the following (whichever occurs first). The primary analysis population is the subset of subjects with an IPI of 3-5. Death due to any causes. Disease progression based on the independent review committee (IRC) assessment per Lugano criteria.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The first secondary objective is to evaluate and compare PFS between the two treatment arms in subjects with newly diagnosed DLBCL with an IPI of 2-5 (i.e., all randomized subjects). The other secondary objectives are to evaluate and compare each key secondary endpoint for both the subset of subjects with an IPI of 3-5 and all randomized subjects per the hierarchical order specified in protocol Section 7.7.

Secondary Endpoints

PFS in all randomized subjects.
CR on or after the EOT based on the IRC assessment per Lugano criteria, where EOT is defined as treatment completion or early treatment discontinuation.
OS, defined as time from randomization until death due to any causes.
MRD negativity.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years old and < 80 years old, with a life expectancy of 12 months. Subject is planned to receive treatment with 6 cycles of standard R CHOP per investigator determination. Subject must have an IPI score of 2-5. The number of subjects with an IPI 2 of will not exceed approximately 30% of the overall sample size.

Exclusion criteria

Subject with history of prior systemic anti-lymphoma therapy for DLBCL (including any definitive radiotherapy with curative intent) other than corticosteroids with or without vincristine during pre-phase treatment, or non-curative intent palliative radiotherapy with the stipulation that radiated lesions cannot be selected as target lesion for response assessment. Subject has clinically significant cardiovascular disease, including: Myocardial infarction or stroke within 6 months prior to enrollment. OR The following conditions within 3 months prior to enrollment: unstable or uncontrolled disease/condition related to or affecting cardiac function (e.g., unstable angina, congestive heart failure, New York Heart Association Class III IV), uncontrolled cardiac arrhythmia OR Screening 12-lead electrocardiogram showing a baseline QT interval as corrected by Fridericia's formula > 470 msec (male) or > 480 msec (female) OR Other clinically significant ECG abnormalities within 6 months prior to enrollment unless deemed stable and appropriately treated.

Calendar

(Last Update: 01/06/2026)

Authorization 15/12/2022	Start of Trial 26/01/2023	First patient inclusion 08/02/2023	Halted Not aported	Restarted Not aported
End of recruitment 15/05/2024	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trial Helpdesk

+4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Sponsor type: Commercial

CeIm

CEIm Provincial de Sevilla

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administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Sites

Active (07/03/2023)	CLINICA UNIVERSIDAD DE NAVARRA Pamplona/Iruña NAVARRA Servicio de Hematología	Clinica Universidad De Navarra Madrid MADRID N/A
Closed (21/10/2024)	Hospital Clinic De Barcelona Barcelona BARCELONA Servicio de Hematología	HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA València VALENCIA Servicio de Hematología
Active (04/03/2024)	Hospital Clínico Universitario Virgen De La Arrixaca Murcia MURCIA Onco Hematología	HOSPITAL DE LA SANTA CREU I SANT PAU Barcelona BARCELONA Servicio de Hematología
Active (25/05/2023)	HOSPITAL DEL MAR. Barcelona BARCELONA Servicio de Hematología	HOSPITAL MD ANDERSON CANCER CENTER MADRID Madrid MADRID Servicio de Hematología

Active (13/06/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

Active (26/06/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Active (21/02/2023)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Servicio de Hematología

Active (02/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Servicio de Hematología

Active (23/02/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Servicio de Hematología

Active (08/03/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D''oncologia

Badalona

BARCELONA

N/A

Active (19/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Active (20/11/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medication

Cyclophosphamide Injection 500 mg.

SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

ATC code: L01AA01 - CICLOFOSFAMIDA

Active Principles: N/A

Experimental

Vincristine Sulfate 1 mg/ml solution for injection

SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

ATC code: L01CA02 - VINCRISTINA

Active Principles: N/A

Experimental

Epcoritamab (GEN3013)

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Active Principles: N/A

Orphan

Experimental

Truxima 100 mg concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

Truxima 500 mg concentrate for solution for infusion

SOLUTION FOR INFUSION
INTRAVENIOUS INFUSION

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

Doxorubicinhydrochlorid Bendalis 2 mg/ml Injektionslösung

SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

ATC code: L01DB01 - DOXORUBICINA

Active Principles: N/A

Experimental

Prednisone Zentiva 5 mg compresse

TABLET
ORAL

ATC code: H02AB07 - PREDNISONA

Active Principles: N/A

Experimental

Epcoritamab (GEN3013)

SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Active Principles: N/A

Orphan

Experimental

No results