

A Study Evaluating the Efficacy and Safety of Pirtobrutinib in Participants With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase II

Participantes esperados

101

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética, dosis

Terapia avanzada

NO

Información

Identificador

2024-515689-15-01 (CTIS)

Cod. Protocolo

J2N-MC-JZNX

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Chronic Lymphocytic Leukemia
Small Lymphocytic Lymphoma

Título Científico

J2N-MC-JZNX: A Phase 2, Open-label, Randomized Study Evaluating the Efficacy and Safety of 3 Doses of Pirtobrutinib in Participants with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Who Previously Received Treatment with a Covalent Bruton Tyrosine Kinase Inhibitor

Justificación

No aportado

Objetivo Principal

To compare the overall response rate of Pirtobrutinib 200 mg to 120 mg, and Pirtobrutinib 200 mg to 60 mg

Variables de Evaluación Primaria

Overall Response Rate

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Have confirmed diagnosis of CLL/SLL as defined by these iwCLL 2018 criteria.
Have received prior CLL/SLL treatment.
Have received at least 1, but not more than 3 lines of prior treatment for CLL/SLL.
Have received a covalent BTK inhibitor.
Have a requirement for therapy consistent with iwCLL 2018 criteria for initiation of therapy.
Capable of swallowing oral study medication.
Have an Eastern Cooperative Oncology Group Performance Status (ECOG) score of 0 to 2.

Criterios de Exclusión

Have received prior treatment with a BTK degrader and a noncovalent BTK inhibitor. Have a history of greater than or equal to ($\geq$) Grade 3 bleeding due to treatment with a BTK inhibitor. Have known or suspected Richters transformation. Have known or suspected history of central nervous system involvement by CLL/SLL. Previous or concurrent cancer distinct from CLL/SLL within 3 years before randomization. Exceptions may occur with documented sponsor approval. Examples include: nonmelanoma skin cancer or lentigo maligna melanoma cervical carcinoma in situ localized prostate cancer undergoing active surveillance, and localized (for example, lymph node negative) breast cancer with no evidence of active disease present for more than 3 years. Individual may be receiving adjuvant hormonal therapy

Calendario

(Última actualización: 03/04/2026)

Autorización 18/02/2025	Inicio de Ensayo 06/03/2025	Inclusión Primer Paciente 12/03/2025	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

Eli Lilly & Co. United States
1 Lilly Corporate Center

Contact Person

Lilly Clinical Trials information desk
00353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Fundación Instituto Valenciano de Oncología

Calle Gregorio Gea 3, Edificio Consultas Externas, 1ª Planta 46009 Valencia

ceim@fivo.org

961104674

Centros

No iniciado (---/---/----)	Clinica Universidad De Navarra Pamplona NAVARRA Hematology
No iniciado (---/---/----)	Clinica Universidad De Navarra Madrid MADRID Hematology
Activo (11/03/2025)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
Activo (13/03/2025)	Hospital Costa Del Sol Marbella MÁLAGA Hematology
Activo (09/04/2025)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Oncology
No iniciado (---/---/----)	Hospital Universitario Central De Asturias Oviedo ASTURIAS Hematology
Activo (15/03/2025)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
Activo (19/03/2026)	Hospital Universitario Infanta Leonor Madrid MADRID Hematology

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (08/03/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (13/03/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Medical Oncology

Activo (07/03/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Cerrado (24/05/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hemathology and hemotherapy

Activo (07/05/2025)

Institut Catala D'´oncologia

Badalona

BARCELONA

Hematology

Activo (07/05/2025)

Institut Catala D'´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (21/03/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Activo (08/03/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Pirtobrutinib

TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

PRD10892569

TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

PRD10916187

TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

Sin resultados

A Study Evaluating the Efficacy and Safety of Pirtobrutinib in Participants With Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

State
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase II

Expected Participants
101

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics, dose

Advanced therapy
NO

Information

Identifier
2024-515689-15-01 (CTIS)

Protocol Code
J2N-MC-JZNX

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Chronic Lymphocytic Leukemia
Small Lymphocytic Lymphoma

Scientific Title
J2N-MC-JZNX: A Phase 2, Open-label, Randomized Study Evaluating the Efficacy and Safety of 3 Doses of Pirtobrutinib in Participants with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Who Previously Received Treatment with a Covalent Bruton Tyrosine Kinase Inhibitor

Rationale

Not provided

Main Objective

To compare the overall response rate of Pirtobrutinib 200 mg to 120 mg, and Pirtobrutinib 200 mg to 60 mg

Primary Endpoints

Overall Response Rate

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Have confirmed diagnosis of CLL/SLL as defined by these iwCLL 2018 criteria.
Have received prior CLL/SLL treatment.
Have received at least 1, but not more than 3 lines of prior treatment for CLL/SLL.
Have received a covalent BTK inhibitor.
Have a requirement for therapy consistent with iwCLL 2018 criteria for initiation of therapy.
Capable of swallowing oral study medication.
Have an Eastern Cooperative Oncology Group Performance Status (ECOG) score of 0 to 2.

Exclusion criteria

Have received prior treatment with a BTK degrader and a noncovalent BTK inhibitor. Have a history of greater than or equal to ($\geq$) Grade 3 bleeding due to treatment with a BTK inhibitor. Have known or suspected Richters transformation. Have known or suspected history of central nervous system involvement by CLL/SLL. Previous or concurrent cancer distinct from CLL/SLL within 3 years before randomization. Exceptions may occur with documented sponsor approval. Examples include: nonmelanoma skin cancer or lentigo maligna melanoma cervical carcinoma in situ localized prostate cancer undergoing active surveillance, and localized (for example, lymph node negative) breast cancer with no evidence of active disease present for more than 3 years. Individual may be receiving adjuvant hormonal therapy

Calendar

(Last Update: 03/04/2026)

Authorization 18/02/2025	Start of Trial 06/03/2025	First patient inclusion 12/03/2025	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Eli Lilly & Co. United States

1 Lilly Corporate Center

Contact Person

Lilly Clinical Trials information desk

00353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Fundación Instituto Valenciano de Oncología

Calle Gregorio Gea 3, Edificio Consultas Externas, 1ª Planta 46009 Valencia

ceim@fivo.org

961104674

Sites

not initialized (---/---/----)	Clinica Universidad De Navarra Pamplona NAVARRA Hematology
not initialized (---/---/----)	Clinica Universidad De Navarra Madrid MADRID Hematology
Active (11/03/2025)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
Active (13/03/2025)	Hospital Costa Del Sol Marbella MÁLAGA Hematology
Active (09/04/2025)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Oncology
not initialized (---/---/----)	Hospital Universitario Central De Asturias Oviedo ASTURIAS Hematology
Active (15/03/2025)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
Active (19/03/2026)	Hospital Universitario Infanta Leonor Madrid MADRID Hematology

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (08/03/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (13/03/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Medical Oncology

Active (07/03/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Closed (24/05/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hemathology and hemotherapy

Active (07/05/2025)

Institut Catala D'´oncologia

Badalona

BARCELONA

Hematology

Active (07/05/2025)

Institut Catala D'´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (21/03/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Active (08/03/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Pirtobrutinib

TABLET

ORAL USE

Active Principles: N/A

Experimental

PRD10892569

TABLET

ORAL USE

Active Principles: N/A

Experimental

PRD10916187

TABLET

ORAL USE

Active Principles: N/A

Experimental

No results