

Ensayo clínico en fase I/II para evaluar la seguridad, tolerabilidad, farmacocinética y eficacia de TERN¿701 en participantes con leucemia mielógena crónica

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Adultos (18-64 años)

Género

Ambos

Fases

Fase I , Fase II

Participantes esperados

116

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

Si

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad, eficacia, farmacocinética

Terapia avanzada

NO

Información

Identificador

2023-507677-18-00 (CTIS)

Cod. Protocolo

TERN701-1012

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

leucemia mielógena crónica

Título Científico

A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

Justificación

No aportado

Objetivo Principal

1. Part 1 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML 2. Part 2 To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Variables de Evaluación Primaria

Part 1 Incidence of DLTs during the first cycle of treatment AE, SAEs, changes in vital signs, laboratory values, and ECG

Part 2 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1 To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Part 2 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML

Variables de Evaluación Secundaria

Part 1 Plasma concentration and derived PK parameters for TERN-701 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Part 2 AE, SAEs, changes in vital signs, laboratory values, and ECG Plasma concentration and derived PK parameters for TERN-701

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male or female participants 18 years of age at the time of signing the informed consent or the legal age of adulthood in countries where the local law considers the legal adult age to be > 18 years of age 2. Have an ECOG performance status score of 0 to 1 3. Have an established cytopathologically confirmed diagnosis of BCR::ABL1 positive CML in CP, and meet at least 1 of the following: For Part 1: Participants without the BCR::ABL1 T315Im who: o Received 2 or more tyrosine kinase inhibitors (TKIs) and have experienced treatment failure, suboptimal response, or treatment intolerance as determined by the investigator OR o Experienced treatment failure or suboptimal response (as determined by the investigator) to frontline therapy with dasatinib, nilotinib, or bosutinib and are ineligible for alternative TKIs per the investigators discretion Participants with BCR::ABL1 T315Im who received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator.; pParticipants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator For Part 2 (randomized dose expansion): Participants who have experienced treatment failure or suboptimal response (as determined by the investigator) to at least 1 but not more than 4 TKIs. Change of TKI due to intolerance without associated treatment failure or suboptimal response will not be counted towards the upper limit of 4 TKIs. 4. Adequate organ function, as assessed by the following screening laboratory values obtained locally: ANC 1500/mm³ Hemoglobin 8.0 g/dL Platelets 100,000/mm³ CrCl 50 mL/min Serum total bilirubin 1.5 × ULN (for participants with Gilberts syndrome, serum total bilirubin 3 × ULN) AST (SGOT) and ALT (SGPT) 2.5 × ULN For Part 2m (mutation cohort): Participants with BCR::ABL1 resistance mutation(s) including T315I, M244V, H396R, E355G, F359I/C/V, and I502L. Other mutations not listed, but present in the P-loop, active site, A-loop, and C-helix, may be considered for inclusion on a case-by-case basis. AND Have received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator. Participants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator

Criterios de Exclusión

1. Peripheral blasts 10%, peripheral basophils 20% and/or additional new clonal chromosomal abnormalities in Ph+ cells 10. Have a history of acute pancreatitis within 1 year of trial entry or chronic pancreatitis 11. Have acute or chronic liver disease (including hepatic encephalopathy, hepatorenal syndrome, or Child-Pugh class B hepatic cirrhosis) 12. Have known significant mental illness or other condition such as active alcohol or other substance abuse or addiction, or other psychosocial conditions, that, in the opinion of the investigator, predisposes the participant to high risk of noncompliance with the protocol; where required by local law, participants will be excluded who are under court protection, persons not affiliated with the local social security system and protected adults 13. Have any of the following cardiovascular conditions: Uncontrolled severe hypertension despite current therapy (blood pressure 150/90 mmHg on more than 1 occasion at least 24 hours apart) within the 28 days prior to the first dose of TERN-701 Symptomatic congestive heart failure, defined as Class II of the New York Heart Association functional classification Recent myocardial infarction (within 3 months) Clinically significant arrhythmias that would preclude participation, in the judgment of the investigator Known history of marked prolongation of QT/QTc interval that, in the judgment of the investigator, would preclude participation QTc interval > 470 ms for women and > 450 ms for men using Fridericias QT correction formula 14. Female participants who are pregnant or lactating 2. CML with atypical transcript (e13a3,e14a3, e8a2, e1a2 and/or e6a2) 3. Mutation Status Exclusions: For Part 1: The following known BCR:ABL1 myristoyl domain resistance mutations: A337V, P465S, V468F, I502L, G463D, G463S, C464W and mutation(s) in the SH2/SH3 contact sites or C lobe For Part 2 randomized dose expansion. The following known mutations in the BCR::ABL1 domain: T315I, M244V, E355D/G/A, A337V, A344V, M351T, P465S, V468F, I502L, G463D, G463S, F359C/V/I, F486S, C464W, mutation(s) in the C-terminal lobe, as well as those in the SH2 and/or SH3 contact sites along with any mutations in the DFG motif (D381, F382, G383) of the activation loop, which extends from the C-lobe 4. Systemic antineoplastic therapy (including prior TKIs, interferon-alfa, therapeutic antibodies, chemotherapy) or other experimental therapy within 7 days or 5 half-lives (whichever is longer) before the first dose of TERN-701; hydroxyurea, if used for leukocytosis, should be weaned off before the first dose of TERN-701 5. Unable to swallow oral medication 6. Have had major surgery within 4 weeks before the start of trial intervention 7. History of significant small bowel resection, gastric bypass, use of feeding tubes or other condition that may preclude adequate absorption of orally dosed trial intervention 8. Have completed previous anticancer therapy without resolution of all associated clinically significant toxicity (to Grade 2 or baseline) prior to TERN-701 administration 9. Prior or concurrent malignancy whose natural history or treatment has the potential to interfere with safety or efficacy assessments per the investigators discretion

Calendario

(Última actualización: 21/08/2026)

Autorización 22/04/2024	Inicio de Ensayo 17/05/2024	Inclusión Primer Paciente 17/05/2024	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

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (13/06/2024)	El Hospital Universitario De Gran Canaria Dr. Negrin Las Palmas De Gran Canaria LAS PALMAS Hematology
Activo (14/05/2024)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
Activo (10/09/2024)	Hospital Germans Trias I Pujol Badalona BARCELONA Hematology
Activo (23/05/2024)	Hospital Quironsalud Zaragoza Zaragoza ZARAGOZA Hematology
Activo (06/06/2024)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology
Activo (26/04/2024)	Hospital Universitario De La Princesa Madrid MADRID Hematology
Activo (07/05/2024)	Hospital Universitario Ramon Y Cajal Madrid MADRID Hematology
Activo (09/05/2024)	Hospital Universitario 12 De Octubre Madrid MADRID Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medicamentos

TERN-701

FILM-COATED TABLET

ORAL

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Principios Activos: N/A

Experimental

TERN-701

FILM-COATED TABLET

ORAL

—

Principios Activos: N/A

Experimental

TERN-701

FILM-COATED TABLET

ORAL

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Principios Activos: N/A

Experimental

Sin resultados

A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

State
Recruiting

Type of participants
Not provided

Age Ranges
Adults (18-64 years)

Gender
Both

Phases
Phase I , Phase II

Expected Participants
116

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness, pharmacokinetics

Advanced therapy
NO

Information

Identifier
2023-507677-18-00 (CTIS)

Protocol Code
TERN701-1012

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Chronic Myeloid Leukemia

Scientific Title
A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

Rationale

Not provided

Main Objective

1. Part 1 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML 2. Part 2 To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Primary Endpoints

Part 1 Incidence of DLTs during the first cycle of treatment AE, SAEs, changes in vital signs, laboratory values, and ECG

Part 2 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1 To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Part 2 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML

Secondary Endpoints

Part 1 Plasma concentration and derived PK parameters for TERN-701 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Part 2 AE, SAEs, changes in vital signs, laboratory values, and ECG Plasma concentration and derived PK parameters for TERN-701

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male or female participants 18 years of age at the time of signing the informed consent or the legal age of adulthood in countries where the local law considers the legal adult age to be > 18 years of age 2. Have an ECOG performance status score of 0 to 1 3. Have an established cytopathologically confirmed diagnosis of BCR::ABL1 positive CML in CP, and meet at least 1 of the following: For Part 1: Participants without the BCR::ABL1 T315I mutation who: o Received 2 or more tyrosine kinase inhibitors (TKIs) and have experienced treatment failure, suboptimal response, or treatment intolerance as determined by the investigator OR o Experienced treatment failure or suboptimal response (as determined by the investigator) to frontline therapy with dasatinib, nilotinib, or bosutinib and are ineligible for alternative TKIs per the investigators discretion Participants with BCR::ABL1 T315I mutation who received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator.; pParticipants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator For Part 2 (randomized dose expansion): Participants who have experienced treatment failure or suboptimal response (as determined by the investigator) to at least 1 but not more than 4 TKIs. Change of TKI due to intolerance without associated treatment failure or suboptimal response will not be counted towards the upper limit of 4 TKIs. 4. Adequate organ function, as assessed by the following screening laboratory values obtained locally: ANC 1500/mm³ Hemoglobin 8.0 g/dL Platelets 100,000/mm³ CrCl 50 mL/min Serum total bilirubin 1.5 × ULN (for participants with Gilberts syndrome, serum total bilirubin 3 × ULN) AST (SGOT) and ALT (SGPT) 2.5 × ULN For Part 2m (mutation cohort): Participants with BCR::ABL1 resistance mutation(s) including T315I, M244V, H396R, E355G, F359I/C/V, and I502L. Other mutations not listed, but present in the P-loop, active site, A-loop, and C-helix, may be considered for inclusion on a case-by-case basis. AND Have received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator. Participants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator

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Calendar

(Last Update: 21/08/2026)

Authorization 22/04/2024	Start of Trial 17/05/2024	First patient inclusion 17/05/2024	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

Terns Inc. United States

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Monetary support: N/A

Sponsor type: Commercial

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Sites

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Active (10/09/2024)	Hospital Germans Trias I Pujol Badalona BARCELONA Hematology	Hospital Quironsalud Zaragoza Zaragoza ZARAGOZA Hematology
Active (06/06/2024)	Hospital Universitari Vall D Hebron Barcelona BARCELONA Hematology	Hospital Universitario De La Princesa Madrid MADRID Hematology
Active (07/05/2024)	Hospital Universitario Ramon Y Cajal Madrid MADRID Hematology	Hospital Universitario 12 De Octubre Madrid MADRID Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

Medication

TERN-701

FILM-COATED TABLET

ORAL

-

Active Principles: N/A

Experimental

TERN-701

FILM-COATED TABLET

ORAL

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Active Principles: N/A

Experimental

TERN-701

FILM-COATED TABLET

ORAL

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Active Principles: N/A

Experimental

No results