

Estudio de fase III de Hetrombopag en pacientes con cifra de trombocitos baja (trombocitopenia) causada por la quimioterapia

Estado Reclutando	Tipo de Participantes No aportado	Rangos de Edad Mayores de 64 , Adultos (18-64 años)
Género Ambos	Fases Fase III	Participantes esperados 63
Resultados Sin resultados	Bajo nivel intervención No	Enfermedad rara No
Cobertura geográfica Sin determinar	Ámbitos del ensayo tratamiento, seguridad, eficacia	Terapia avanzada NO

Información

Identificador 2025-524209-34-00 (CTIS)	Cod. Protocolo SHR8735-303
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Área terapéutica
Not possible to specify|

Enfermedad investigada
Trombocitopenia inducida por la quimioterapia

Título Científico
Estudio de fase III, aleatorizado, multicéntrico y doble ciego para evaluar la eficacia y la seguridad de comprimidos de hetrombopag olamina en comparación con placebo en pacientes con trombocitopenia inducida por la quimioterapia

Justificación

No aportado

Objetivo Principal

Partea A ¿Evaluarea caracteristicilor farmacocinetice (FC) ale hetrombopagului la participanți non-asiatici cu trombocitopenie indusă de chimioterapie (TIC).

Partea B ¿Evaluarea eficacității clinice a tratamentului cu hetrombopag la participanții cu TIC.

Variables de Evaluación Primaria

Parte A: Los parámetros FC (p. ej., C_{max} , $ABC_{0-\infty}$, C_{min}) de hetrombopag en participantes no asiáticos con TIQ.

Parte B: Proporción de pacientes que responden al tratamiento y cumplen estos criterios:

- 1) CP $\geq 100 \times 10^9/l$ en 14d después de iniciar el medicamento en investigación (incl. D14)
- 2) Completar 2 ciclos de quimio consecutivos (C1 y C2) sin modificación inducida por trombocitopenia de ningún fármaco mielodepresor
- 3) No deberá utilizarse ningún tratamiento de rescate para la trombocitopenia desde el inicio del tratamiento con el MI hasta el final del periodo de tratamiento principal

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Parte A

¿Evaluar la eficacia y la seguridad del tratamiento con hetrombopag en participantes no asiáticos con TIQ.

Parte B

¿Evaluar la seguridad del tratamiento con hetrombopag en participantes con TIQ.

Parte B ¿Evaluar la seguridad del tratamiento con hetrombopag en participantes con TIQ

Variables de Evaluación Secundaria

Proportion of participants who completed two consecutive on-study chemotherapy cycles without thrombocytopenia-induced modification of any myelosuppressive agent. Proportion of participants achieving PC $100 \times 10^9 /L$ without the use of rescue therapy within 14 days after initiating the IP treatment (including Day 14) Proportion of participants with at least a single incidence of rescue therapy. Time to rescue therapy free first platelet response of PC $100 \times 10^9/L$ defined as the interval between the initiation of IP treatment and the first platelet response. Cumulative duration of platelet response of PC $100 \times 10^9/L$ without the use of rescue therapy. PC nadir from C1D1 until the end of the primary treatment period. Cumulative duration of severe thrombocytopenia, defined as the number of consecutive days with a PC of $50 \times 10^9/L$. Proportion of participants who completed two consecutive on-study chemotherapy cycles without treatment regimen modification. Proportion of participants with all cause events leading to treatment regimen modifications including dose reduction, delay, omission, or discontinuation. Proportion of participants who

are free from serious bleeding events, defined as Grade ≥ 2 per the World Health Organization (WHO) bleeding scale, from the initiation of IP treatment until the end of the primary treatment period. Number and proportion of participants with adverse events (AEs)/serious adverse events (SAEs), safety laboratory parameters, vital signs, etc. Proportion of participants with neutropenia during the treatment period from the initiation of IP treatment until the end of the primary treatment period. Proportion of non-Asian treatment responders who meet the following criteria (Part A only): 1) Platelet count (PC) of $100 \times 10^9/L$ within 14 days after initiating the IP treatment (incl. Day 14); 2) Complete two consecutive on-study chemotherapy cycles (C1 and C2) without thrombocytopenia-induced modification of any myelosuppressive agent; 3) No use of any rescue therapy for thrombocytopenia from the initiation of IP treatment until the end of the primary treatment period.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Sexo masculino o femenino; edad ≥ 18 años en la selección (o edad legal local para otorgar el consentimiento). Tumor sólido confirmado histológica o citológicamente. Recibir tratamientos de quimioterapia con platino o gemcitabina en ciclos de tratamiento de 14 o 21 días. CP $< 85 \times 10^9/l$ en el momento de la inclusión. Tener un retraso en el tratamiento definido por el protocolo de ≥ 7 días por ciclo de quimioterapia debido a TIQ con CP $< 85 \times 10^9/l$ (solo la parte B). Estado funcional según el Grupo Oncológico Cooperativo de la Costa Este de los EE. UU. (EF según el ECOG) de 0-2. Función orgánica y hematológica adecuada. Tener raza y etnia no asiática (solo la Parte A)

Criterios de Exclusión

CP $< 25 \times 10^9/l$ en la selección. Enfermedades hepatopoyéticas distintas de la TIQ (p. ej., trombocitopenia inmunitaria primaria). Neoplasias malignas hematológicas. Metástasis cerebrales no tratadas; o con metástasis leptomeningea. Infiltrado en la médula ósea documentado que causa trombocitopenia refractaria o > 3 metástasis óseas conocidas con daño cortical óseo o lesiones líticas o blásticas. Acontecimientos trombóticos arteriales o venosos con intolerancia al tratamiento anticoagulante durante ≥ 6 semanas. Hemorragia grave (p. ej., hemorragia gastrointestinal o intracraneal) en los 28 días anteriores al día 1 del estudio. Sangrado de grado ≥ 2 según la OMS dentro de los 14 días previos a la selección

Calendario

(Última actualización: 07/08/2026)

Autorización 27/04/2026	Inicio de Ensayo 29/05/2026	Inclusión Primer Paciente 29/05/2026	Interrumpido No aportado	Reiniciado No aportado
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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
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Promotor

Jiangsu Hengrui Pharmaceuticals Co. Ltd. China
7 Kunlunshan RoadEconomic And Technological Development Zone

Contact Person

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Monetary support: N/A
Tipo de promotor: Comercial

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Centros

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

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Ourense

OURENSE

Oncology

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

Hospital Universitari Arnau De Vilanova De La Gerencia Territorial De Lleida

Lleida

LÉRIDA

Oncology

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

Hospital Universitari General De Catalunya

Sant Cugat Del Valles

BARCELONA

Oncology

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

Hospital Universitario De Torrejon

Torrejon De Ardoz

MADRID

Oncology

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Oncology

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Oncology

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Oncology

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

Micancer Center S.L.P.

Barcelona

BARCELONA

Pratia ES Sirius Barcelona Cl&iacute;nica Tres Torres, Oncology

Medicamentos

Hetrombopag Olamine
FILM COATED TABLET
ORAL

Principios Activos: N/A

Experimental

Sin resultados

A Phase 3 study of Hetrombopag in patients with low blood platelet count (thrombocytopenia) caused by chemotherapy

State
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase III

Expected Participants
63

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
treatment, safety, effectiveness

Advanced therapy
NO

Information

Identifier
2025-524209-34-00 (CTIS)

Protocol Code
SHR8735-303

Therapeutic area
Not possible to specify|

Investigated Disease
Chemotherapy induced thrombocytopenia

Scientific Title
A Randomized, Multi-Center, Double-Blind, Phase III Study Evaluating the Efficacy and Safety of Hetrombopag Olamine Tablets vs Placebo in Patients with Chemotherapy-Induced Thrombocytopenia

Rationale

Not provided

Main Objective

Part A

To evaluate the pharmacokinetic (PK) characteristics of hetrombopag in non-Asian participants with chemotherapy-induced thrombocytopenia (CIT).

Part B

To evaluate the efficacy of hetrombopag treatment in participants with CIT.

Primary Endpoints

Part A: PK parameters (e.g., Cmax, AUC0-tau, Cmin) of hetrombopag in non-Asian participants with CIT.

Proportion of treatment responders meeting these criteria: 1.) PC 100×10^9 /L within 14 days after initiating IMP treatment (incl Day 14); 2.) Complete two consecutive on-study chemotherapy cycles (C1 and C2) without thrombocytopenia-induced modification of any myelosuppressive agent; 3.) No use of any rescue therapy for thrombocytopenia during the treatment period from the initiation of IP treatment until the end of the primary treatment period.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part A To evaluate the efficacy and safety of hetrombopag treatment in nonAsian participants with CIT.

Part B To evaluate the safety of hetrombopag treatment in participants with CIT.

Secondary Endpoints

Proportion of participants who completed two consecutive on-study chemotherapy cycles without thrombocytopenia-induced modification of any myelosuppressive agent. Proportion of participants achieving PC 100×10^9 /L without the use of rescue therapy within 14 days after initiating the IP treatment (including Day 14) Proportion of participants with at least a single incidence of rescue therapy. Time to rescue therapy free first platelet response of PC 100×10^9 /L defined as the interval between the initiation of IP treatment and the first platelet response. Cumulative duration of platelet response of PC 100×10^9 /L without the use of rescue therapy. PC nadir from C1D1 until the end of the primary treatment period. Cumulative duration of severe thrombocytopenia, defined as the number of consecutive days with a PC of 50×10^9 /L. Proportion of participants who completed two consecutive on-study chemotherapy cycles without treatment regimen modification. Proportion of participants with all cause events leading to treatment regimen modifications including dose reduction, delay, omission, or discontinuation. Proportion of participants who are free from serious bleeding events, defined as Grade ≥ 2 per the World Health Organization (WHO) bleeding scale, from the initiation of IP treatment until the end of the primary treatment period. Number and proportion of

participants with adverse events (AEs)/serious adverse events (SAEs), safety laboratory parameters, vital signs, etc. Proportion of participants with neutropenia during the treatment period from the initiation of IP treatment until the end of the primary treatment period. Proportion of non-Asian treatment responders who meet the following criteria (Part A only): 1) Platelet count (PC) of $100 \times 10^9/L$ within 14 days after initiating the IP treatment (incl. Day 14); 2) Complete two consecutive on-study chemotherapy cycles (C1 and C2) without thrombocytopenia-induced modification of any myelosuppressive agent; 3) No use of any rescue therapy for thrombocytopenia from the initiation of IP treatment until the end of the primary treatment period.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Male or female gender, age 18 years at screening (or local age of consent). Histologically or cytologically confirmed solid tumor Receiving platinum- and/or gemcitabine-containing chemotherapy regimens on 14-day or 21-day treatment cycles. PC $< 85 \times 10^9/L$ at enrollment. Experiencing a protocol-defined treatment delay of 7 days per chemotherapy cycle due to CIT with PC $< 85 \times 10^9/L$ (Part B only). Eastern Cooperative Oncology Group performance status (ECOG PS) 0-2. Adequate organ and hematologic function Having non-Asian race and ethnicity (Part A only).

Exclusion criteria

PC $< 85 \times 10^9/L$ at enrollment. Hematopoietic diseases other than CIT (e.g., primary immune thrombocytopenia). Hematologic malignancies Untreated brain metastases; or with leptomeningeal metastasis. Documented bone marrow infiltration causing refractory thrombocytopenia or > 3 known bone metastases with cortical bone damage or lytic or blastic lesions. Arterial or venous thrombotic events with anticoagulation therapy not being tolerated 6 weeks. Severe hemorrhage (e.g., gastrointestinal, or intracranial hemorrhage) within 28 days prior to enrollment WHO grade 2 bleeding within 14 days prior to screening.

Calendar

(Last Update: 07/08/2026)

Authorization 27/04/2026	Start of Trial 29/05/2026	First patient inclusion 29/05/2026	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

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Medication

Hetrombopag Olamine

FILM COATED TABLET

ORAL

Active Principles: N/A

Experimental

No results