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

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

Información

Identificador
2025-524209-34-00 (CTIS)

Cod. Protocolo
SHR8735-303

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 participan¿i non-asiatici cu trombocitopenie indus¿ de chimioterapie (TIC).
Partea B ¿Evaluarea eficacit¿¿ii clinice a tratamentului cu hetrombopag la participan¿ii cu TIC.

Variables de Evaluación Primaria

Parte A: Los parámetros FC (p. ej., Cmáx, ABC0-¿, Cmín) de hetrombopag en participantes no asiáticos con TIQ.
Parte B: Proporción de pacientes que responden al tratamiento y cumplen estos criterios:
1)CP ¿100×109/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 100×109 /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 100×109/L defined as the interval between the initiation of IP treatment and the first platelet response. Cumulative duration of platelet response of PC 100×109/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 50×109/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 100×109/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 <85×109/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 <85×109/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 <25×109/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 leptomeníngea. 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	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/04/2026	29/05/2026	29/05/2026	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

Jiangsu Hengrui Pharmaceuticals Co. Ltd. China

7 Kunlunshan RoadEconomic And Technological Development Zone

Contact Person

Hengrui Clinical Trials EU

0041798015748

EUClinicalTrials@hengrui.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Germans Trias i Pujol

Ctra. Canyet, s/n Edificio General - 1a planta / Módulos urgencias - 1a planta 08916 Badalona

ceic.germanstrias@gencat.cat

934978956

Centros

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

Complejo Hospitalario Universitario De Ourense

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 Clínica 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	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	63
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	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 100×109 /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 100×109 /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 100×109/L defined as the interval between the initiation of IP treatment and the first platelet response. Cumulative duration of platelet response of PC 100×109/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 50×109/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 100×109/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 <85×109/L at enrollment. Experiencing a protocol-defined treatment delay of 7 days per chemotherapy cycle due to CIT with PC <85×109/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

PC85×109/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	Start of Trial	First patient inclusion	Halted	Restarted
27/04/2026	29/05/2026	29/05/2026	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

Jiangsu Hengrui Pharmaceuticals Co. Ltd. China

7 Kunlunshan RoadEconomic And Technological Development Zone

Contact Person

Hengrui Clinical Trials EU

0041798015748

EUClinicalTrials@hengrui.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Germans Trias i Pujol

Ctra. Canyet, s/n Edificio General - 1a planta / Módulos urgencias - 1a planta 08916 Badalona

ceic.germanstrias@gencat.cat

934978956

Sites

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

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Oncology

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

Hospital Universitari Arnau De Vilanova De La Gerencia Territorial De Lleida

Lleida

LÉRIDA

Oncology

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

Hospital Universitari General De Catalunya

Sant Cugat Del Valles

BARCELONA

Oncology

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

Hospital Universitario De Torrejon

Torrejon De Ardoz

MADRID

Oncology

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Oncology

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Oncology

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Oncology

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

Micancer Center S.L.P.

Barcelona

BARCELONA

Pratia ES Sirius Barcelona Clínica Tres Torres, Oncology

Medication

Hetrombopag Olamine
FILM COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

No results