

Pacritinib for Patients With Myelofibrosis Who Have Thrombocytopenia

Estado Reclutando	Tipo de Participantes No aportado	Rangos de Edad Mayores de 64 , Adultos (18-64 años)
Género Ambos	Fases Fase II	Participantes esperados 30
Resultados Sin resultados	Bajo nivel intervención No	Enfermedad rara No
Cobertura geográfica Sin determinar	Ámbitos del ensayo tratamiento	Terapia avanzada NO

Información

Identificador 2025-522509-39-00 (CTIS)	Cod. Protocolo GEMFIN-MF-PACRI 2401
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Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Patients with myelofibrosis and platelets counts between 50 - 120 x 10e9/L

Título Científico
Pacritinib For The Reduction Of Bone Marrow Fibrosis In Patients With Myelofibrosis Who Have Thrombocytopenia; A Multicenter, Open-Label, Single Arm, Phase II Exploratory Study

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to evaluate the effect of pacritinib on the bone marrow fibrosis.

Variables de Evaluación Primaria

Decrease of 1 grade in reticulin fibrosis from baseline to week 52 measured in bone marrow biopsy.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of pacritinib in bone marrow fibrosis reduction, measured by quantitative Dixon Quant magnetic resonance imaging (MRI)

To correlate changes in fat content/cellularity (FF) by MRI with fibrosis assessment by BM biopsy.

To evaluate anemia response: a) To assess the red blood cell (RBC) transfusion independence rate achieved with pacritinib. b) To evaluate the changes in Hb level achieved with pacritinib, in patients who are transfusion-independent. c) To correlate changes in fat content/cellularity (by MRI) and fibrosis assessment (by BM biopsy) with anemia response.

To evaluate the durability of anemia response under pacritinib treatment.

To evaluate the changes in platelet counts

To evaluate the effect of pacritinib on the durability of platelet response under pacritinib.

To determine the effect of pacritinib in the VAF of driver-gen.

To correlate changes in fat content/cellularity (FF) by MRI and/or fibrosis assessment by BM biopsy with the splenic, anemia and platelet response, as well as, with the changes in the VAF of driver-gen.

To correlate pacritinib-induced changes in the VAF of driver-gen with the splenic, anemia and platelet response.

To evaluate safety of the intended treatment regimen based on the frequency and severity of adverse events and Treatment-emergent adverse events (TEAEs) assessed by NCI CTCAE v5.0.

To evaluate the treatment compliance of pacritinib.

To identify predicted biomarker of response in blood and BM in patients with MF: To evaluate the inflammatory cytokines profile under pacritinib treatment. To assess gene/protein expression of TGF-1 and NFkB targets .

To evaluate the effect of pacritinib in the bone marrow fibrosis at early time-points

To evaluate the efficacy of pacritinib in bone marrow fibrosis reduction measured by quantitative Dixon Quant magnetic resonance imaging (MRI) at early time-points.

To correlate changes in fat content/cellularity (FF) by MRI and fibrosis assessment by BM biopsy marrow at early time-points.

To evaluate the changes in MPN symptoms during pacritinib treatment.

To evaluate the efficacy of pacritinib to reduce the spleen volume by MRI from baseline and its durability among patients with baseline splenomegaly

Variables de Evaluación Secundaria

Improvement in bone marrow fat fraction (FF) at Week 52 (C12D1) from baseline, measured by quantitative MRI as has been previously described

Percent change in fat fraction by quantitative Dixon Quant MRI will be correlated with improvement in BM fibrosis by at least 1 grade (assessment by BM biopsy) at Week 52.

To evaluate anemia response a) Achievement of RBC transfusion independence over the first 24 weeks of treatment. b) Improvement in hemoglobin level without transfusion over the first 24 weeks of treatment c) Correlation study between i) the changes in hemoglobin level without transfusion and/or proportion of patients achievement of RBC transfusion independence with ii) the changes in the Bone Marrow (by MRI and/or BM biopsy) over the first 24 weeks of treatment.

Durability of anemia response a) Achievement of RBC transfusion independence over the first 52 weeks of treatment. b) Improvement in hemoglobin level without transfusion over the first 52 weeks of treatment c) Correlation study between i) the changes in hemoglobin level without transfusion and/or proportion of patients achievement of RBC transfusion independence with ii) the changes in in the Bone Marrow (by MRI and/or BM biopsy) over the first 52 weeks

Improvement in platelet counts without transfusion at week 24 from baseline

Improvement in platelet counts without transfusion at week 52 from baseline

Post-treatment changes in MPN driver-gen VAF (JAK2, CALR, MPL) from baseline at Week 24 and Week 52.

Percent change in fat fraction by quantitative Dixon Quant MRI and/or in the grade of fibrosis in BM will be correlated with the percent change in splenic volume; with the percent change in the driver-gen VAF; and with the hemoglobin and platelet levels at Week 24 and Week 52.

Post-treatment changes in MPN driver-gen VAF will be correlated with the percent change in splenic volume; and with the hemoglobin and platelet levels at Week 24 and Week 52

Frequency and severity of adverse events and Treatment-related adverse events (TRAEs) assessed by NCI CTCAE v5.0

Rate of completion of pacritinib treatment: Cumulative dose Actual dose intensity Relative dose intensity Proportion of patients requiring dose interruptions Proportion of patients requiring dose reductions

Assesment of MF or dual IRAK-1/JAK2 inhibitor (pacritinib) biology-related features associated with response: Changes in the levels of circulating plasma cytokines at week 24 from baseline by Luminex Changes in the mRNA and/or protein expression levels of of TGT betha and NFkB targets will be measures at week 24 in bone marrow and compare between responders and non-responders to pacritinib.

Decrease of 1 grade in reticulin fibrosis from baseline to week 24 measured in bone marrow biopsy.

Improvement in bone marrow fat fraction (FF) at Week 24 from baseline, measured by quantitative MRI

Percent change in fat fraction by quantitative Dixon Quant MRI and improvement in BM histology (assessment by BM biopsy) at Week 24.

Changes in MPN symptoms throughout the study period assessed through MPN SAF TSS 2.0 questionnaire

Percent change in splenic volume at Week 24 and Week 52 among patients with baseline splenomegaly

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Signed written and voluntary informed consent. Adequate coagulation defined by prothrombin time/international normalized ratio and partial thromboplastin time $1.5 \times$ ULN. If fertile, willing to use effective birth control methods during the study and up to 30 days after the last dose of pacritinib Willing to undergo and able to tolerate frequent MRI during the study and BM biopsy Able to understand and willing to complete symptom assessments. Age 18 years Patients with a confirmed diagnosis of myelofibrosis, either primary myelofibrosis (PMF) or post polycythemia vera (PPV-MF) or post essential thrombocythemia (PET-MF) Patients with thrombocytopenia, delimited by platelets

counts between 50 - 120 x10e9/L. Patients who require JAK-2 inhibitor therapy in the opinion of the investigator and are eligible to start treatment with pacritinib either in the first line (JAK2 inhibitor-naïve) or in second line setting (after no response or loss of response or intolerance to one prior JAK2 inhibitor). Note: patients should have recovered to grade 1 from any toxicity from previous treatment. Have a Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0 - 2 Have a dynamic international prognostic scoring system (DIPSS) Intermediate-1, Intermediate-2, or High risk Peripheral blasts count < 5% and absolute neutrophil count (ANC) of 500/L. Adequate liver and renal function, defined by: a. liver transaminases, including alanine aminotransferase (ALT or GOT) and aspartate aminotransferase (AST or GOT) 3 x upper limit normal (ULN). AST/ALT 5 x ULN if transaminase elevation is related to MF. b. Total bilirubin and/or direct bilirubin 4 x ULN. c. Estimated glomerular filtration rate (eGFR) > 30 mL/min.

Criterios de Exclusión

Life expectancy <6 months. Any active GI or metabolic condition that could interfere with absorption of oral medication. Splenic irradiation within the last 6 months. Previously treated with pacritinib. Concurrent enrollment in another interventional trial. Treatment with an experimental therapy within 28 days prior to the first dose of study treatment. Systemic treatment with a strong CYP3A4 inhibitor or inducer and the treatment cannot be either discontinued or switched to a different medication within 5 half-lives prior to study entry. Severe (Child-Pugh C) liver impairment. Significant recent bleeding history defined as NCI CTCAE grade 2 within 3 months prior to first dose of study treatment, or with active bleeding, unless precipitated by an inciting event (e.g., surgery, trauma, or injury). Conditions or medications that increase the risk of bleeding, except for aspirin (dosages of 100 mg per day). Patients treated with "direct-acting oral anticoagulants (DOACs), could be considered for inclusion (may be consulted with the Sponsor, GEMFIN). Patients with rheumatoid arthritis for whom therapy with an alternative JAK inhibitor is required Any history of CTCAE grade 2 dysrhythmias or non-dysrhythmia cardiac conditions within 6 months prior to the first dose of study treatment. Patients with non-dysrhythmia or non-QTc grade 2 cardiovascular conditions , may be considered for inclusion, if stable , asymptomatic and unlikely to affect patient safety. QT corrected by the Fridericia method (QTcF) prolongation >480 ms or other factors that increase the risk for QTcF interval prolongation (e.g., heart failure, hypokalemia or history of long QT interval syndrome). New York Heart Association Class II, III, or IV congestive heart failure. Active or uncontrolled inflammatory or chronic functional bowel disorder such as Crohns disease, inflammatory bowel disease, chronic diarrhea or constipation Other malignancy within 3 years prior to treatment Day 1, other than curatively treated basal cell or squamous cell skin or corneal cancer; curatively treated carcinoma in situ of the cervix. The exception is if patients have been disease-free for at least 5 years, and are deemed by the investigator to be at low risk for recurrence of that malignancy. Known seropositivity for human immunodeficiency virus. Known active hepatitis B, or C virus infection. Women who are pregnant or lactating Uncontrolled intercurrent illness, including, but not limited to, ongoing active infection, psychiatric illness, or social situation that, in the judgment of the treating physician, would limit compliance with study requirements.

Calendario

(Última actualización: 27/07/2026)

Autorización 06/02/2026	Inicio de Ensayo 30/03/2026	Inclusión Primer Paciente 15/04/2026	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

Grupo Español de Enfermedades Mieloproliferativas Crónicas Filadelfia Negativas País no aportado
N/A

Contact Person

GEMFIN Secretariat

0034934344412

investigacion@mfar.net

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

CEIm Hospital Fundación Jiménez Díaz

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915443720

Centros

Activo (12/05/2026)	Consortio Hospital General Universitario De Valencia Valencia VALENCIA Hematology Department	No iniciado (---/---/----)	El Hospital Universitario De Gran Canaria Dr. Negrín Las Palmas De Gran Canaria LAS PALMAS Hematology Department
Activo (10/04/2026)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology Department	Activo (22/06/2026)	Hospital Clinico Universitario De Valencia Valencia VALENCIA Hematology Department
Activo (27/07/2026)	Hospital De Jerez De La Frontera Jerez De La Frontera CÁDIZ Hematology Department	Activo (05/05/2026)	Hospital Del Mar Barcelona BARCELONA Hematology Department
Activo (08/04/2026)	Hospital General Universitario Gregorio Marañón Madrid MADRID Hematology Department	Activo (15/04/2026)	Hospital General Universitario Morales Meseguer Murcia MURCIA Hematology Department

Activo (17/06/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology Department

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology Department

Activo (31/03/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology Department

Activo (09/04/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology Department

Activo (10/04/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology Department

Medicamentos

Pacritinib

CAPSULE, HARD

ORAL USE

Principios Activos: N/A

Experimental

Sin resultados

Pacritinib for Patients With Myelofibrosis Who Have Thrombocytopenia

State
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase II

Expected Participants
30

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
treatment

Advanced therapy
NO

Information

Identifier
2025-522509-39-00 (CTIS)

Protocol Code
GEMFIN-MF-PACRI 2401

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Patients with myelofibrosis and platelets counts between 50 - 120 x 10e9/L

Scientific Title
Pacritinib For The Reduction Of Bone Marrow Fibrosis In Patients With Myelofibrosis Who Have Thrombocytopenia;
A Multicenter, Open-Label, Single Arm, Phase II Exploratory Study

Rationale

Not provided

Main Objective

The primary objective of this study is to evaluate the effect of pacritinib on the bone marrow fibrosis.

Primary Endpoints

Decrease of 1 grade in reticulin fibrosis from baseline to week 52 measured in bone marrow biopsy.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of pacritinib in bone marrow fibrosis reduction, measured by quantitative Dixon Quant magnetic resonance imaging (MRI)

To correlate changes in fat content/cellularity (FF) by MRI with fibrosis assessment by BM biopsy.

To evaluate anemia response: a) To assess the red blood cell (RBC) transfusion independence rate achieved with pacritinib. b) To evaluate the changes in Hb level achieved with pacritinib, in patients who are transfusion-independent. c) To correlate changes in fat content/cellularity (by MRI) and fibrosis assessment (by BM biopsy) with anemia response.

To evaluate the durability of anemia response under pacritinib treatment.

To evaluate the changes in platelet counts

To evaluate the effect of pacritinib on the durability of platelet response under pacritinib.

To determine the effect of pacritinib in the VAF of driver-gen.

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To evaluate the efficacy of pacritinib to reduce the spleen volume by MRI from baseline and its durability among patients with baseline splenomegaly

Secondary Endpoints

Improvement in bone marrow fat fraction (FF) at Week 52 (C12D1) from baseline, measured by quantitative MRI as has been previously described

Percent change in fat fraction by quantitative Dixon Quant MRI will be correlated with improvement in BM fibrosis by at least 1 grade (assessment by BM biopsy) at Week 52.

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Changes in MPN symptoms throughout the study period assessed through MPN SAF TSS 2.0 questionnaire

Percent change in splenic volume at Week 24 and Week 52 among patients with baseline splenomegaly

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Signed written and voluntary informed consent. Adequate coagulation defined by prothrombin time/international normalized ratio and partial thromboplastin time $1.5 \times$ ULN. If fertile, willing to use effective birth control methods during the study and up to 30 days after the last dose of pacritinib Willing to undergo and able to tolerate frequent MRI during the study and BM biopsy Able to understand and willing to complete symptom assessments. Age 18 years Patients with a confirmed diagnosis of myelofibrosis, either primary myelofibrosis (PMF) or post polycythemia vera (PPV-MF) or post essential thrombocythemia (PET-MF) Patients with thrombocytopenia, delimited by platelets

counts between 50 - 120 x10e9/L. Patients who require JAK-2 inhibitor therapy in the opinion of the investigator and are eligible to start treatment with pacritinib either in the first line (JAK2 inhibitor-naïve) or in second line setting (after no response or loss of response or intolerance to one prior JAK2 inhibitor). Note: patients should have recovered to grade 1 from any toxicity from previous treatment. Have a Eastern Cooperative Oncology Group Performance Status (ECOG-PS) of 0 - 2 Have a dynamic international prognostic scoring system (DIPSS) Intermediate-1, Intermediate-2, or High risk Peripheral blasts count < 5% and absolute neutrophil count (ANC) of 500/L. Adequate liver and renal function, defined by: a. liver transaminases, including alanine aminotransferase (ALT or GOT) and aspartate aminotransferase (AST or GOT) 3 x upper limit normal (ULN). AST/ALT 5 x ULN if transaminase elevation is related to MF. b. Total bilirubin and/or direct bilirubin 4 x ULN. c. Estimated glomerular filtration rate (eGFR) > 30 mL/min.

Exclusion criteria

Life expectancy <6 months. Any active GI or metabolic condition that could interfere with absorption of oral medication. Splenic irradiation within the last 6 months. Previously treated with pacritinib. Concurrent enrollment in another interventional trial. Treatment with an experimental therapy within 28 days prior to the first dose of study treatment. Systemic treatment with a strong CYP3A4 inhibitor or inducer and the treatment cannot be either discontinued or switched to a different medication within 5 half-lives prior to study entry. Severe (Child-Pugh C) liver impairment. Significant recent bleeding history defined as NCI CTCAE grade 2 within 3 months prior to first dose of study treatment, or with active bleeding, unless precipitated by an inciting event (e.g., surgery, trauma, or injury). Conditions or medications that increase the risk of bleeding, except for aspirin (dosages of 100 mg per day). Patients treated with "direct-acting oral anticoagulants (DOACs), could be considered for inclusion (may be consulted with the Sponsor, GEMFIN). Patients with rheumatoid arthritis for whom therapy with an alternative JAK inhibitor is required Any history of CTCAE grade 2 dysrhythmias or non-dysrhythmia cardiac conditions within 6 months prior to the first dose of study treatment. Patients with non-dysrhythmia or non-QTc grade 2 cardiovascular conditions , may be considered for inclusion, if stable , asymptomatic and unlikely to affect patient safety. QT corrected by the Fridericia method (QTcF) prolongation >480 ms or other factors that increase the risk for QTcF interval prolongation (e.g., heart failure, hypokalemia or history of long QT interval syndrome). New York Heart Association Class II, III, or IV congestive heart failure. Active or uncontrolled inflammatory or chronic functional bowel disorder such as Crohns disease, inflammatory bowel disease, chronic diarrhea or constipation Other malignancy within 3 years prior to treatment Day 1, other than curatively treated basal cell or squamous cell skin or corneal cancer; curatively treated carcinoma in situ of the cervix. The exception is if patients have been disease-free for at least 5 years, and are deemed by the investigator to be at low risk for recurrence of that malignancy. Known seropositivity for human immunodeficiency virus. Known active hepatitis B, or C virus infection. Women who are pregnant or lactating Uncontrolled intercurrent illness, including, but not limited to, ongoing active infection, psychiatric illness, or social situation that, in the judgment of the treating physician, would limit compliance with study requirements.

Calendar

(Last Update: 27/07/2026)

Authorization 06/02/2026	Start of Trial 30/03/2026	First patient inclusion 15/04/2026	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

Grupo Español de Enfermedades Mieloproliferativas Crónicas Filadelfia Negativas País no aportado
N/A

Contact Person

GEMFIN Secretariat
0034934344412
investigacion@mfar.net

Monetary support: N/A
Sponsor type: No commercial

Ceim

CEIm Hospital Fundación Jiménez Díaz
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915443720

Sites

Active (12/05/2026)	Consortio Hospital General Universitario De Valencia Valencia VALENCIA Hematology Department
not initialized (---/---/----)	El Hospital Universitario De Gran Canaria Dr. Negrin Las Palmas De Gran Canaria LAS PALMAS Hematology Department
Active (10/04/2026)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology Department
Active (22/06/2026)	Hospital Clinico Universitario De Valencia Valencia VALENCIA Hematology Department
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Active (17/06/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology Department

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology Department

Active (31/03/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology Department

Active (09/04/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology Department

Active (10/04/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology Department

Medication

Pacritinib
CAPSULE, HARD
ORAL USE

Active Principles: N/A

Experimental

No results