# Pacritinib para pacientes con mielofibrosis y trombocitopenia

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

## Información

### Identificador
2025-522509-39-00 (CTIS)

### Cod. Protocolo
GEMFIN-MF-PACRI 2401

### Área terapéutica
Enfermedades [C] - Cáncer [C04]|

### Enfermedad investigada
Pacientes con mielofibrosis y recuentos de plaquetas entre 50 y 120 x 10e9/L)

### Título Científico
Pacritinib para la reducción de la fibrosis de la médula ósea en pacientes con mielofibrosis y trombocitopenia: estudio exploratorio multicéntrico, abierto, de un solo grupo y de fase II

## Justificación

No aportado

## Objetivo Principal

El objetivo principal de este estudio es evaluar el efecto de pacritinib sobre la fibrosis de la médula ósea.

## Variables de Evaluación Primaria

Disminución de ¿1 grado en la fibrosis de reticulina desde el inicio hasta la semana 52 medida en la biopsia de médula ósea

## Momentos temporales de evaluación primaria

No aportado

## Objetivo Secundario

Evaluar la eficacia de pacritinib en la reducción de la fibrosis de la médula ósea, medida mediante resonancia magnética cuantitativa Dixon Quant (RM)
Correlacionar los cambios en el contenido de grasa/celularidad (FF) por resonancia magnética con la evaluación de fibrosis mediante biopsia de médula ósea.
Para evaluar la respuesta a la anemia:
a) Evaluar la tasa de independencia transfusional de glóbulos rojos lograda con pacritinib.
b) Evaluar los cambios en el nivel de Hb logrados con pacritinib en pacientes independientes de transfusiones.
c) Correlacionar los cambios en el contenido graso/celularidad (mediante resonancia magnética) y la evaluación de la fibrosis (mediante biopsia de médula ósea) con la respuesta a la anemia.
Evaluar la durabilidad de la respuesta a la anemia bajo el tratamiento con pacritinib.
Evaluar los cambios en el recuento de plaquetas
Evaluar el efecto de pacritinib sobre la durabilidad de la respuesta plaquetaria bajo tratamiento con pacritinib.
Determinar el efecto de pacritinib en el VAF del gen conductor.
Correlacionar los cambios en el contenido de grasa/celularidad (FF) por resonancia magnética y/o evaluación de fibrosis por biopsia de médula ósea con la respuesta esplénica, anémica y plaquetaria, así como con los cambios en el VAF del gen conductor.
Correlacionar los cambios inducidos por pacritinib en el VAF del gen conductor con la respuesta esplénica, anémica y plaquetaria.
Evaluar la seguridad del régimen de tratamiento previsto en función de la frecuencia y la gravedad de los eventos adversos y los eventos adversos emergentes del tratamiento (EAET) evaluados por NCI CTCAE v5.0.
Evaluar el cumplimiento del tratamiento con pacritinib.
Identificar biomarcadores de respuesta predictivos en sangre y médula ósea en pacientes con MF:
¿ Evaluar el perfil de citocinas inflamatorias durante el tratamiento con pacritinib.
¿ Evaluar la expresión génica/proteica de dianas de TGF-¿1 y NFkB.
Evaluar el efecto del pacritinib en la fibrosis de la médula ósea en puntos temporales tempranos.
Evaluar la eficacia de pacritinib en la reducción de la fibrosis de la médula ósea medida mediante resonancia magnética cuantitativa Dixon Quant (MRI) en puntos temporales tempranos.
Correlacionar los cambios en el contenido de grasa/celularidad (FF) mediante resonancia magnética y la evaluación

de la fibrosis mediante biopsia de médula ósea en puntos temporales tempranos.
Evaluar los cambios en los síntomas de MPN durante el tratamiento con pacritinib.
Evaluar la eficacia de pacritinib para reducir el volumen del bazo mediante resonancia magnética desde el inicio y su durabilidad entre pacientes con esplenomegalia basal

## 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
Assessement 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

Consentimiento informado escrito y voluntario firmado. Coagulación adecuada definida por el tiempo de protrombina/índice internacional normalizado y el tiempo de tromboplastina parcial ¿ 1,5 × LSN. Si es fértil, está dispuesta a utilizar métodos anticonceptivos efectivos durante el estudio y hasta 30 días después de la última dosis de pacritinib. Dispuesto a someterse y poder tolerar resonancias magnéticas frecuentes durante el estudio y biopsia de médula ósea. Capaz de comprender y dispuesto a completar evaluaciones de síntomas. Edad ¿18 años Pacientes con diagnóstico confirmado de mielofibrosis, ya sea mielofibrosis primaria (PMF) o post policitemia vera (PPV-MF) o post trombocitemia esencial (PET-MF) Pacientes con trombocitopenia, delimitada por recuentos de plaquetas entre 50 ¿ 120 x10e9/L. Pacientes que, a juicio del investigador, requieren tratamiento con inhibidores de JAK-2 y son elegibles para iniciar el tratamiento con pacritinib, ya sea en primera línea (sin tratamiento previo con inhibidores de JAK2) o en segunda línea (tras ausencia de respuesta, pérdida de respuesta o intolerancia a un inhibidor de JAK2 previo). Nota: Los pacientes deben haberse recuperado a grado ¿ 1 de cualquier toxicidad del tratamiento previo. Tener un estado funcional del Eastern Cooperative Oncology Group (ECOG-PS) de 0 a 2 Tener un sistema de puntuación pronóstica internacional dinámico (DIPSS) de riesgo intermedio-1, intermedio-2 o alto. Recuento de blastos periféricos < 5% y recuento absoluto de neutrófilos (RAN) de ¿500/¿L. Función hepática y renal adecuada, definida por: a. Transaminasas hepáticas, incluyendo alanina aminotransferasa (ALT) y aspartato aminotransferasa (AST) ¿ 3 x LSN. AST/ALT ¿ 5 x LSN si la elevación de transaminasas está relacionada con MF. b. Bilirrubina total y/o bilirrubina directa ¿ 4 x LSN. c. Tasa de filtración glomerular estimada (TFGe) > 30 ml/min

## Criterios de Exclusión

Esperanza de vida <6 meses. Cualquier condición gastrointestinal o metabólica activa que pueda interferir con la absorción de la medicación oral. Irradiación esplénica en los últimos 6 meses. Tratado previamente con pacritinib. Inclusión concurrente en otro ensayo intervencionista. Tratamiento con una terapia experimental dentro de los 28 días previos a la primera dosis del tratamiento del estudio. Tratamiento sistémico con un inhibidor o inductor potente del CYP3A4 y el tratamiento no puede suspenderse ni cambiarse a un medicamento diferente dentro de las 5 vidas medias anteriores a la inclusión al estudio. Insuficiencia hepática grave (Child-Pugh C). Antecedentes de sangrado reciente significativo, definidos como grado ¿2 de NCI CTCAE dentro de los 3 meses previos a la primera dosis del tratamiento del estudio, o con sangrado activo, a menos que sea precipitado por un evento desencadenante (p. ej., cirugía, traumatismo o lesión). Afecciones o medicamentos que aumentan el riesgo de sangrado, excepto aspirina (dosis ¿100 mg al día). Se podría considerar la inclusión de pacientes tratados con anticoagulantes orales de acción directa (ACOD) (puede consultarse con el promotor, GEMFIN). Pacientes con artritis reumatoide para quienes se requiere terapia con un inhibidor de JAK alternativo. Antecedentes de arritmias de grado ¿2 según CTCAE o afecciones cardíacas no arritmicas en los 6 meses previos a la primera dosis del tratamiento del estudio. Se podrá considerar la inclusión de pacientes con afecciones cardiovasculares de grado 2 no arritmicas o sin QTc si se encuentran estables, asintomáticos y es improbable que afecten a la seguridad del paciente. Prolongación del intervalo QT corregido por el método de Fridericia (QTcF) >480 ms u otros factores que aumentan el riesgo de prolongación del intervalo QTcF (p. ej., insuficiencia cardíaca, hipocalemia o antecedentes de síndrome de intervalo QT largo). Insuficiencia cardíaca congestiva de clase II, III o IV de la New York Heart Association. Trastorno intestinal inflamatorio o funcional crónico activo o no controlado, como enfermedad de Crohn, enfermedad inflamatoria intestinal, diarrea crónica o estreñimiento. Otra neoplasia maligna en los 3 años previos al día 1 de tratamiento, excepto cáncer de piel o córnea de células basales o de células escamosas con tratamiento curativo; carcinoma in situ de cuello uterino con tratamiento curativo. La excepción es si las pacientes han estado libres de enfermedad durante al menos 5 años y el investigador considera que tienen bajo riesgo de recurrencia de dicha neoplasia. Seropositividad conocida para el virus de la inmunodeficiencia humana. Infección activa conocida por el virus de la hepatitis B o C. Mujeres embarazadas o en período de lactancia Enfermedad intercurrente no controlada, que incluye, entre otras, infección activa en curso, enfermedad psiquiátrica o situación social que, a juicio del médico tratante, limitaría el cumplimiento de los requisitos del estudio

# Calendario

(Última actualización: 05/10/2026)

| Autorización | Inicio de Ensayo | Inclusión Primer Paciente | Interrumpido | Reiniciado |
|---|---|---|---|---|
| 06/02/2026 | 30/03/2026 | 15/04/2026 | 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

## Grupo Espanol De Enfermedades Mieloproliferativas Cronicas Ph Spain

**C Secretari Coloma Num. 64 68Esc. B Planta Ent Puerta 05**

**Contact Person**

GEMFIN Secretariat

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**Monetary support: N/A**

**Tipo de promotor: No comercial**

# Ceim

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**915443720**

# Centros

Activo (12/05/2026)

**Consorcio Hospital General Universitario De Valencia**

Valencia

VALENCIA

Hematology Department

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

**El Hospital Universitario De Gran Canaria Dr. Negrin**

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 Maranon**

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

Activo (21/09/2026)

**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** | **Type of participants** | **Age Ranges** |
| Recruiting | Not provided | Older than 64 , Adults (18-64 years) |
| **Gender** | **Phases** | **Expected Participants** |
| Both | Phase II | 30 |
| **Results** | **Low level of intervention** | **Rare disease** |
| No results | No | No |
| **Geographic coverage** | **Areas of the study** | **Advanced therapy** |
| Undetermined | treatment | 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.
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

## 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.
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
Assessement 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

## 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 × 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-naive) 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 × 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-lifes 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: 05/10/2026)

| Authorization | Start of Trial | First patient inclusion | Halted | Restarted |
|---|---|---|---|---|
| 06/02/2026 | 30/03/2026 | 15/04/2026 | 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

## Grupo Espanol De Enfermedades Mieloproliferativas Cronicas Ph Spain

**C Secretari Coloma Num. 64 68Esc. B Planta Ent Puerta 05**

**Contact Person**

GEMFIN Secretariat

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**Monetary support: N/A**

**Sponsor type: No commercial**

# Ceim

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# Sites

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**Consorcio Hospital General Universitario De Valencia**

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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

Active (27/07/2026)

**Hospital De Jerez De La Frontera**

Jerez De La Frontera

CÁDIZ

Hematology Department

Active (05/05/2026)

**Hospital Del Mar**

Barcelona

BARCELONA

Hematology Department

Active (08/04/2026)

**Hospital General Universitario Gregorio Maranon**

Madrid

MADRID

Hematology Department

Active (15/04/2026)

**Hospital General Universitario Morales Meseguer**

Murcia

MURCIA

Hematology Department

Active (17/06/2026)

**Hospital Universitari Vall D Hebron**

Barcelona

BARCELONA

Hematology Department

Active (21/09/2026)

**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