A study to compare Venetoclax Azacitidine and Quizartinib Vs Venetoclax and Azacitidine in newly diagnosed acute myeloid leukemia patient´s ineligible for standard induction chemotherapy

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	56
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2025-522979-29-00 (CTIS)

Cod. Protocolo
VENP-A-QUI

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

Enfermedad investigada
Acute myeloid leukemia

Título Científico
A randomized phase III, global, multicentre, open label clinical trial comparing Venetoclax Azacitidine and Quizartinib vs Venetoclax and Azacitidine in newly diagnosed acute myeloid leukemia patient´s ineligible for standard induction chemotherapy.

Justificación

No aportado

Objetivo Principal

To compare the OS rate between the experimental arm with triple combination of venetoclax, azacitidine and quizartinib vs. standard therapy (venetoclax plus azacitidine)

Variables de Evaluación Primaria

Overall survival (OS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Key secondary objective: To compare the event-free survival (EFS) rate (failure to achieve CR/CRi/CRh after 4 cycles, death in CR/CRi/CRh or relapse, whichever occurs the first) between the experimental arm with triple combination and standard arm.
Key secondary objective: To evaluate the CR/CRi/CRh (composite complete response [CCR]) rate (best response obtained on study).
To evaluate the CR/CRi/CRh with negative measurable residual disease (MRD) by next generation sequencing (NGS) after 1, 4 and 9 cycles of standard therapy or experimental arm with quizartinib.
To assess safety and tolerability of experimental arm and standard arm.
To compare the overall hematologic and non-hematologic toxicity of the standard and experimental arm.
To compare the relapse-free survival (RFS) (time to events, death in CR/CRi/CRh or relapse, whichever occurs the first), cumulative incidence of relapse (CIR), and non-relapse mortality (NRM) between the experimental and standard arms.
Subanalyses on efficacy and safety in different populations (FLT3-ITD, FLT3-TKD, NPM1, IDH, P53, and other).
To evaluate early mortality (first 30 and 60 days since randomization).
To evaluate the impact on the quality of life, using the EQ5D and the EORTC Quality of Life Questionnaire-Core 30 (QLQ-C30) forms, of standard therapy or experimental arm.
To evaluate the impact on the use of medical resources during treatment phase (ie, antibiotics, transfusions, duration of hospitalization, use of triazoles).
Safety parameters including changes in clinical laboratory measures (clinical chemistry, hematology, coagulation, urinalysis), vital signs, electrocardiograms (ECGs), the incidence and severity of adverse events (AEs), and the incidence of serious adverse events (SAEs) and deaths.
Biomarker plans to gain insight into the mechanism of action of quizartinib in FLT3-ITD negative AML.

Variables de Evaluación Secundaria

Event-free survival (EFS)
Composite CR (CCR) (best response obtained on study)
Early mortality (first 30 and 60 days)
CR, CRh, and CRi with negative measurable residual disease (MRD) by NGS
CR, CRh, CRi and CCR at 1, 4 and 9 cycles of treatment
Time to CR, CRh, CRi, CCRCR, CRi, MLFS, PR, PD
Relapse-free survival (RFS)
Cumulative incidence of relapse (CIR)
Duration of response (DoR)
Quality of life measurements (from the EuroQoL Group EQ-5D-5L and the EORTC QLQ-C30 instruments)
Medical resources during treatement phase
Rates of RBC and platelet transfusion independence, duration of RBC transfusion independence and platelet transfusion independence and platelet and RBC transfusion independence
Minimal residual disease (MRD) by NGS
Separate analyses in secondary AML, CBF, FLT3-ITD, FLT3 other, NPM1, P53, IDH1/IDH2, and subsets

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

The subject must have confirmation of AML by 2022 WHO criteria, previously untreated and be ineligible for treatment with a standard cytarabine and anthracycline based induction regimen due to age and/or comorbidities. Patients must be considered ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age or co-morbidities defined by the following criteria: - 75 years of age; - or 18 to 75 years of age with at least one of the following co-morbidities: ECOG Performance Status of 2 or 3; Cardiac history of cardiac heart failure (CHF) requiring treatment or left ventricular ejection fraction (LVEF) >45% and 55% or chronic stable angina. DLCO 65% or FEV1 65% and/or significant history of chronic pulmonary obstructive; Creatinine clearance 30 mL/min to < 50 ml/min (see Appendix 7); Moderate hepatic impairment with total bilirubin, SGPT or SGOT > 1.5 to 3.0 × ULN; Non active/controlled prior neoplastic disease; Any other patient´s comorbidity or disease condition that the physician judges to be incompatible with intensive chemotherapy must be reviewed and approved by the Clinical Trial Coordinator before study enrollment (e.g, prior neoplastic disease, high-risk cytogenetics). All patients aged less than 60 years old must be reviewed and approved by Clinical Trial Coordinator before study enrollment. ECOG performance status 2 for patients >75 years, 3 for patients 60 to 75 years of age. Male subjects who are sexually active, must agree, from Study Day 1 through at least 120 days after the last dose of study drug, to practice the protocol specified contraception (see Section 7.9). Female subjects must be either postmenopausal for at least 1 year before screening OR permanently surgical sterile (bilateral oophorectomy, bilateral salpingectomy or hysterectomy) or Women of Childbearing Potential (WOCBP) must agree to practice 1 highly effective method and 1 additional effective (barrier) method of contraception, at the same time, from the time of signing the informed consent through 7 months after the last dose of study drug (female and male condoms should not be used together), or Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [e.g., calendar, ovulation, symptothermal, postovulation methods] withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception). Female subjects of childbearing potential must have negative results for pregnancy test performed and must not be lactating and breastfeeding. Subject must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to the initiation of any screening or study specific procedures, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.

Criterios de Exclusión

Age <18 years old at screening. Contraindications for Azacitidine, Quizartinib or Venetoclax (such as history of hypersensitivity to any excipients in Azacitidine, Quizartinib, or Venetoclax). Known central nervous system (CNS) active leukemia, including cerebrospinal fluid positive for AML blasts. Prior treatment with any investigational drug or device within 14 days prior to Randomization (within 2 weeks for investigational or approved immunotherapy) or currently participating in other investigational interventional procedures. Known uncontrolled or significant cardiovascular disease, including any of the following: a) Bradycardia of less than 50 beats per minute, unless the subject has a pacemaker; b) QTcF interval >450 msec in males, >470 in female patients; c) Diagnosis of or suspicion of long QT syndrome (including family history of long QT syndrome); d) Systolic blood pressure 180 mmHg or diastolic blood pressure 110 mmHg; e) History of clinically relevant ventricular arrhythmias (eg, ventricular tachycardia, ventricular fibrillation, or Torsade de Pointes); f) History of second (Mobitz II) or third degree heart block (subjects with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker); g) History of uncontrolled angina pectoris or myocardial infarction within 6 months prior to Screening; h) History of New York Heart Association Class 3 or 4 heart failure; i) Known history of LVEF 45%; j) Complete left bundle branch block; k) Severe aortic stenosis Prior therapy for AML (except hydroxiurea, or maximum 1 gram/sqm per 2 days of cytarabine allowed to control hyperleukocytosis during the screening period). Subject must not have consumed grapefruit, grapefruit products, Seville oranges (including marmalade-containing Seville oranges), or star fruit within 3 days before anticipated first dose of Venetoclax and must consent not to consume through the last dose of Venetoclax. Active acute or chronic systemic fungal, bacterial, or viral infection not well controlled by antifungal, antibacterial or antiviral therapy at physician discretion. Known active clinically relevant liver disease (eg, active hepatitis B, or active hepatitis C) Known history of human immunodeficiency virus (HIV). Uncorrected Grade 3 or 4 hypokalemia, hypomagnesemia or hypocalcemia (Subjects with Grade 1 or 2 electrolyte abnormalities can be enrolled while electrolytes are being corrected). Subject has received prior treatment with hypomethylating agent, FLT3 or BCL2 inhibitors. Uncontrolled hypothyroidism. Confirmed diagnosis of prior myelodysplastic syndrome (MDS) or a myeloproliferative neoplasm (MPN) or MDS/MPNs including CMML, aCML, JMML and others. This exclusion criterion will not be applicable to patients with with FLT3 (allelic ratio >0.03) or NPM1 mutations (as per technical sensitivity threshold of local and/or central laboratory), who can be enrolled. Genetic diagnosis of acute promyelocytic leukemia. Treated (excluding surgery or hormone-therapy) for another malignancy within 6 months before randomization or previously diagnosed with another malignancy and have any evidence of disease which may compromise the administration of investigational treatment schedule. Presence of any severe psychiatric disease or physical condition that, according to the physician´s criteria, contraindicates the inclusion of the patient into the clinical trial. Serum creatinine 2.5 mg/dL or creatinine clearance < 30 mL/min (unless it is attributable to AML activity). Bilirubin >1.5 times, SGPT or SGOT > 3 times the upper normal limit (unless it is attributable to AML activity). WBC >25 x 109/L before randomization.

Calendario

(Última actualización: 31/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/12/2025	30/04/2026	07/05/2026	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

Fundacion PETHEMA Spain

Oficinas 3 4 5Calle De Santa Balbina 2

Contact Person

Alfonso Santiago

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIM Área de Salud de Salamanca

Pº San Vicente nº 55-182 37007 Salamanca

comite.etico.husa@saludcastillayleon.es

923291100

Centros

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

Althaia Xarxa Assistencial Universitaria De Manresa Fundacio Privada

Manresa

BARCELONA

Hematología

Activo (24/06/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematología

Activo (21/08/2026)

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Hematología

Activo (13/08/2026)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematología

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

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematología

Activo (30/07/2026)

Consorci Sanitari De Terrassa

Terrassa

BARCELONA

Hematología

Activo (02/07/2026)

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Hematología

Activo (29/07/2026)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematología

Activo (03/07/2026)

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Hematología

Activo (15/07/2026)

Hospital Arnau De Vilanova De Valencia

Valencia

VALENCIA

Hematología

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

Hospital Clinico San Carlos

Madrid

MADRID

Hematología

Activo (09/07/2026)

Hospital De Galdakao Usansolo

Galdakao

VIZCAYA/BIZKAIA

Hematología

Activo (09/06/2026)

Hospital General De Segovia

Segovia

SEGOVIA

Hematología

Activo (03/07/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematología

Activo (22/06/2026)

Hospital General Universitario De Castellon

Castello De La Plana

CASTELLÓN

Hematología

Activo (26/05/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematología

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

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Hematología

Activo (08/05/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematología

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

Hospital Universitario Basurto

Bilbao

VIZCAYA/BIZKAIA

Hematología

Activo (27/05/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematología

Activo (15/07/2026)

Hospital Universitario De Canarias

San Cristobal De La Laguna

STA. CRUZ DE TENERIFE

Hematología

Activo (18/06/2026)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Hematología

Activo (28/07/2026)

Hospital Universitario De Jaen

Jaen

JAÉN

Hematología

Activo (11/06/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematología

Activo (21/08/2026)

Hospital Universitario De Toledo

Toledo

TOLEDO

Hematología

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

Hospital Universitario Donostia

Donostia

GUIPÚZCOA

Hematología

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

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematología

Activo (28/08/2026)

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematología

Activo (03/07/2026)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematología

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

Hospital Universitario Infanta Sofía

San Sebastian De Los Reyes

MADRID

Hematología

Activo (05/06/2026)

Hospital Universitario Juan Ramon Jimenez

Huelva

HUELVA

Hematología

Activo (23/06/2026)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Hematología

Activo (01/07/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematología

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

Hospital Universitario Nuestra Senora De Candelaria

Santa Cruz De Tenerife

STA. CRUZ DE TENERIFE

Hematología

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

Hospital Universitario Principe De Asturias

Alcala De Henares

MADRID

Hematología

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematología

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

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Hematología

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematología

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematología

Activo (01/07/2026)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematología

Activo (27/05/2026)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematología

Activo (24/07/2026)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Hematología

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

Hospital Universitario Torrecardenas

Almeria

ALMERÍA

Hematología

Activo (15/07/2026)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematología

Activo (27/05/2026)

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Hematología

Activo (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematología

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematología

Activo (27/05/2026)

Hospital Virgen Del Puerto

Plasencia

CÁCERES

Hematología

Activo (11/08/2026)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematología

Activo (15/07/2026)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematología

Activo (08/07/2026)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematología

Activo (27/05/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematología

Medicamentos

Quizartinib
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Sin resultados

A study to compare Venetoclax Azacitidine and Quizartinib Vs Venetoclax and Azacitidine in newly diagnosed acute myeloid leukemia patient´s ineligible for standard induction chemotherapy

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	56
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2025-522979-29-00 (CTIS)

Protocol Code
VENP-A-QUI

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Acute myeloid leukemia

Scientific Title
A randomized phase III, global, multicentre, open label clinical trial comparing Venetoclax Azacitidine and Quizartinib vs Venetoclax and Azacitidine in newly diagnosed acute myeloid leukemia patient´s ineligible for standard induction chemotherapy.

Rationale

Not provided

Main Objective

To compare the OS rate between the experimental arm with triple combination of venetoclax, azacitidine and quizartinib vs. standard therapy (venetoclax plus azacitidine)

Primary Endpoints

Overall survival (OS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Key secondary objective: To compare the event-free survival (EFS) rate (failure to achieve CR/CRi/CRh after 4 cycles, death in CR/CRi/CRh or relapse, whichever occurs the first) between the experimental arm with triple combination and standard arm.
Key secondary objective: To evaluate the CR/CRi/CRh (composite complete response [CCR]) rate (best response obtained on study).
To evaluate the CR/CRi/CRh with negative measurable residual disease (MRD) by next generation sequencing (NGS) after 1, 4 and 9 cycles of standard therapy or experimental arm with quizartinib.
To assess safety and tolerability of experimental arm and standard arm.
To compare the overall hematologic and non-hematologic toxicity of the standard and experimental arm.
To compare the relapse-free survival (RFS) (time to events, death in CR/CRi/CRh or relapse, whichever occurs the first), cumulative incidence of relapse (CIR), and non-relapse mortality (NRM) between the experimental and standard arms.
Subanalyses on efficacy and safety in different populations (FLT3-ITD, FLT3-TKD, NPM1, IDH, P53, and other).
To evaluate early mortality (first 30 and 60 days since randomization).
To evaluate the impact on the quality of life, using the EQ5D and the EORTC Quality of Life Questionnaire-Core 30 (QLQ-C30) forms, of standard therapy or experimental arm.
To evaluate the impact on the use of medical resources during treatment phase (ie, antibiotics, transfusions, duration of hospitalization, use of triazoles).
Safety parameters including changes in clinical laboratory measures (clinical chemistry, hematology, coagulation, urinalysis), vital signs, electrocardiograms (ECGs), the incidence and severity of adverse events (AEs), and the incidence of serious adverse events (SAEs) and deaths.
Biomarker plans to gain insight into the mechanism of action of quizartinib in FLT3-ITD negative AML.

Secondary Endpoints

Event-free survival (EFS)
Composite CR (CCR) (best response obtained on study)
Early mortality (first 30 and 60 days)
CR, CRh, and CRi with negative measurable residual disease (MRD) by NGS
CR, CRh, CRi and CCR at 1, 4 and 9 cycles of treatment
Time to CR, CRh, CRi, CCRCR, CRi, MLFS, PR, PD
Relapse-free survival (RFS)
Cumulative incidence of relapse (CIR)
Duration of response (DoR)
Quality of life measurements (from the EuroQoL Group EQ-5D-5L and the EORTC QLQ-C30 instruments)
Medical resources during treatement phase
Rates of RBC and platelet transfusion independence, duration of RBC transfusion independence and platelet transfusion independence and platelet and RBC transfusion independence
Minimal residual disease (MRD) by NGS
Separate analyses in secondary AML, CBF, FLT3-ITD, FLT3 other, NPM1, P53, IDH1/IDH2, and subsets

Temporary moments of secondary assessment

Not provided

Inclusion criteria

The subject must have confirmation of AML by 2022 WHO criteria, previously untreated and be ineligible for treatment with a standard cytarabine and anthracycline based induction regimen due to age and/or comorbidities. Patients must be considered ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age or co-morbidities defined by the following criteria: - 75 years of age; - or 18 to 75 years of age with at least one of the following co-morbidities: ECOG Performance Status of 2 or 3; Cardiac history of cardiac heart failure (CHF) requiring treatment or left ventricular ejection fraction (LVEF) >45% and 55% or chronic stable angina. DLCO 65% or FEV1 65% and/or significant history of chronic pulmonary obstructive; Creatinine clearance 30 mL/min to < 50 ml/min (see Appendix 7); Moderate hepatic impairment with total bilirubin, SGPT or SGOT > 1.5 to 3.0 × ULN; Non active/controlled prior neoplastic disease; Any other patient´s comorbidity or disease condition that the physician judges to be incompatible with intensive chemotherapy must be reviewed and approved by the Clinical Trial Coordinator before study enrollment (e.g, prior neoplastic disease, high-risk cytogenetics). All patients aged less than 60 years old must be reviewed and approved by Clinical Trial Coordinator before study enrollment. ECOG performance status 2 for patients >75 years, 3 for patients 60 to 75 years of age. Male subjects who are sexually active, must agree, from Study Day 1 through at least 120 days after the last dose of study drug, to practice the protocol specified contraception (see Section 7.9). Female subjects must be either postmenopausal for at least 1 year before screening OR permanently surgical sterile (bilateral oophorectomy, bilateral salpingectomy or hysterectomy) or Women of Childbearing Potential (WOCBP) must agree to practice 1 highly effective method and 1 additional effective (barrier) method of contraception, at the same time, from the time of signing the informed consent through 7 months after the last dose of study drug (female and male condoms should not be used together), or Agree to practice true abstinence, when this is in line with the preferred and usual lifestyle of the subject. (Periodic abstinence [e.g., calendar, ovulation, symptothermal, postovulation methods] withdrawal, spermicides only, and lactational amenorrhea are not acceptable methods of contraception). Female subjects of childbearing potential must have negative results for pregnancy test performed and must not be lactating and breastfeeding. Subject must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to the initiation of any screening or study specific procedures, with the understanding that consent may be withdrawn by the patient at any time without prejudice to future medical care.

Exclusion criteria

Age <18 years old at screening. Contraindications for Azacitidine, Quizartinib or Venetoclax (such as history of hypersensitivity to any excipients in Azacitidine, Quizartinib, or Venetoclax). Known central nervous system (CNS) active leukemia, including cerebrospinal fluid positive for AML blasts. Prior treatment with any investigational drug or device within 14 days prior to Randomization (within 2 weeks for investigational or approved immunotherapy) or currently participating in other investigational interventional procedures. Known uncontrolled or significant cardiovascular disease, including any of the following: a) Bradycardia of less than 50 beats per minute, unless the subject has a pacemaker; b) QTcF interval >450 msec in males, >470 in female patients; c) Diagnosis of or suspicion of long QT syndrome (including family history of long QT syndrome); d) Systolic blood pressure 180 mmHg or diastolic blood pressure 110 mmHg; e) History of clinically relevant ventricular arrhythmias (eg, ventricular tachycardia, ventricular fibrillation, or Torsade de Pointes); f) History of second (Mobitz II) or third degree heart block (subjects with pacemakers are eligible if they have no history of fainting or clinically relevant arrhythmias while using the pacemaker); g) History of uncontrolled angina pectoris or myocardial infarction within 6 months prior to Screening; h) History of New York Heart Association Class 3 or 4 heart failure; i) Known history of LVEF 45%; j) Complete left bundle branch block; k) Severe aortic stenosis Prior therapy for AML (except hydroxiurea, or maximum 1 gram/sqm per 2 days of cytarabine allowed to control hyperleukocytosis during the screening period). Subject must not have consumed grapefruit, grapefruit products, Seville oranges (including marmalade-containing Seville oranges), or star fruit within 3 days before anticipated first dose of Venetoclax and must consent not to consume through the last dose of Venetoclax. Active acute or chronic systemic fungal, bacterial, or viral infection not well controlled by antifungal, antibacterial or antiviral therapy at physician discretion. Known active clinically relevant liver disease (eg, active hepatitis B, or active hepatitis C) Known history of human immunodeficiency virus (HIV). Uncorrected Grade 3 or 4 hypokalemia, hypomagnesemia or hypocalcemia (Subjects with Grade 1 or 2 electrolyte abnormalities can be enrolled while electrolytes are being corrected). Subject has received prior treatment with hypomethylating agent, FLT3 or BCL2 inhibitors. Uncontrolled hypothyroidism. Confirmed diagnosis of prior myelodysplastic syndrome (MDS) or a myeloproliferative neoplasm (MPN) or MDS/MPNs including CMML, aCML, JMML and others. This exclusion criterion will not be applicable to patients with with FLT3 (allelic ratio >0.03) or NPM1 mutations (as per technical sensitivity threshold of local and/or central laboratory), who can be enrolled. Genetic diagnosis of acute promyelocytic leukemia. Treated (excluding surgery or hormone-therapy) for another malignancy within 6 months before randomization or previously diagnosed with another malignancy and have any evidence of disease which may compromise the administration of investigational treatment schedule. Presence of any severe psychiatric disease or physical condition that, according to the physician´s criteria, contraindicates the inclusion of the patient into the clinical trial. Serum creatinine 2.5 mg/dL or creatinine clearance < 30 mL/min (unless it is attributable to AML activity). Bilirubin >1.5 times, SGPT or SGOT > 3 times the upper normal limit (unless it is attributable to AML activity). WBC >25 x 109/L before randomization.

Calendar

(Last Update: 31/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/12/2025	30/04/2026	07/05/2026	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

Fundacion PETHEMA Spain

Oficinas 3 4 5Calle De Santa Balbina 2

Contact Person

Alfonso Santiago

+34916266232

gerencia@fundacionpethema.es

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIM Área de Salud de Salamanca

Pº San Vicente nº 55-182 37007 Salamanca

comite.etico.husa@saludcastillayleon.es

923291100

Sites

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

Althaia Xarxa Assistencial Universitaria De Manresa Fundacio Privada

Manresa

BARCELONA

Hematología

Active (24/06/2026)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematología

Active (21/08/2026)

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Hematología

Active (13/08/2026)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematología

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

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematología

Active (30/07/2026)

Consorci Sanitari De Terrassa

Terrassa

BARCELONA

Hematología

Active (02/07/2026)

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Hematología

Active (29/07/2026)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematología

Active (03/07/2026)

Hospital Alvaro Cunqueiro

Vigo

PONTEVEDRA

Hematología

Active (15/07/2026)

Hospital Arnau De Vilanova De Valencia

Valencia

VALENCIA

Hematología

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

Hospital Clinico San Carlos

Madrid

MADRID

Hematología

Active (09/07/2026)

Hospital De Galdakao Usansolo

Galdakao

VIZCAYA/BIZKAIA

Hematología

Active (09/06/2026)

Hospital General De Segovia

Segovia

SEGOVIA

Hematología

Active (03/07/2026)

Hospital General Universitario De Albacete

Albacete

ALBACETE

Hematología

Active (22/06/2026)

Hospital General Universitario De Castellon

Castello De La Plana

CASTELLÓN

Hematología

Active (26/05/2026)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematología

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

Hospital Moncloa Grupo Hla S.A.

Madrid

MADRID

Hematología

Active (08/05/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematología

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

Hospital Universitario Basurto

Bilbao

VIZCAYA/BIZKAIA

Hematología

Active (27/05/2026)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematología

Active (15/07/2026)

Hospital Universitario De Canarias

San Cristobal De La Laguna

STA. CRUZ DE TENERIFE

Hematología

Active (18/06/2026)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Hematología

Active (28/07/2026)

Hospital Universitario De Jaen

Jaen

JAÉN

Hematología

Active (11/06/2026)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematología

Active (21/08/2026)

Hospital Universitario De Toledo

Toledo

TOLEDO

Hematología

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

Hospital Universitario Donostia

Donostia

GUIPÚZCOA

Hematología

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

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematología

Active (28/08/2026)

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematología

Active (03/07/2026)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematología

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

Hospital Universitario Infanta Sofía

San Sebastian De Los Reyes

MADRID

Hematología

Active (05/06/2026)

Hospital Universitario Juan Ramon Jimenez

Huelva

HUELVA

Hematología

Active (23/06/2026)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Hematología

Active (01/07/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematología

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

Hospital Universitario Nuestra Senora De Candelaria

Santa Cruz De Tenerife

STA. CRUZ DE TENERIFE

Hematología

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

Hospital Universitario Principe De Asturias

Alcala De Henares

MADRID

Hematología

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematología

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

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Hematología

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

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematología

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematología

Active (01/07/2026)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematología

Active (27/05/2026)

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Hematología

Active (24/07/2026)

Hospital Universitario Rio Hortega

Valladolid

VALLADOLID

Hematología

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

Hospital Universitario Torrecardenas

Almeria

ALMERÍA

Hematología

Active (15/07/2026)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematología

Active (27/05/2026)

Hospital Universitario Virgen De Valme

Sevilla

SEVILLA

Hematología

Active (30/04/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematología

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematología

Active (27/05/2026)

Hospital Virgen Del Puerto

Plasencia

CÁCERES

Hematología

Active (11/08/2026)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematología

Active (15/07/2026)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematología

Active (08/07/2026)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematología

Active (27/05/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematología

Medication

Quizartinib
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

Quizartinib
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

No results