A Study of Bleximenib, Venetoclax and Azacitidine For Treatment of Participants With Newly Diagnosed Acute Myeloid Leukemia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	338
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, eficacia	NO

Información

Identificador
2024-520154-38-00 (CTIS)

Cod. Protocolo
75276617AML3001

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

Enfermedad investigada
Acute Myeloid Luekemia

Título Científico
A Phase 3 Randomized, Double-blind, Placebo-controlled, Study of Bleximenib, Venetoclax and Azacitidine for the Treatment of Participants with Newly Diagnosed Acute Myeloid Leukemia Harboring KMT2ARearrangements or NPM1Mutations who are Ineligible for Intensive Chemotherapy

Justificación

No aportado

Objetivo Principal

To compare the efficacy of bleximenib and VEN+AZA vs VEN+AZA alone

Variables de Evaluación Primaria

Dual primary endpoints: CR and OS

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Be 18 years of age (or the legal age of majority in the jurisdiction in which the study is taking place, whichever is greater) at the time of informed consent. 2. Previously untreated KMT2Ar or NPM1m AML with 10% blasts per 2022 ICC criteria. -Participants with KMT2A partial tandem duplications or amplifications are NOT eligible. - Emergency leukapheresis and/or cytoreductive therapy with hydroxyurea and/or to a total of 2 g/m2 cytarabine (cytarabine may be administered over a maximum of 5 days, not to exceed 3 doses) is permitted prior to first dose of study treatment. Note: cytoreductive therapy with cytarabine should not be given until after the screening bone marrow assessment. Leukapheresis and cytarabine must be discontinued 1 day prior to first dose of study treatment. 3. Ineligible for intensive chemotherapy based on the following criteria: 75 years of age and ineligible per physicians discretion, with ECOG performance status of 0-2 18 to <75 years of age with 1 of the following comorbidities: ECOG performance status of 2 Severe cardiac disorder (eg, congestive heart failure requiring treatment or chronic stable angina) Severe

pulmonary disorder (eg, DLCO 65% or FEV1 65%) Renal impairment defined as eGFR (MDRD formula) Comorbidity that, in the investigators opinion, makes the participant unsuitable for intensive chemotherapy, which must be documented before enrollment. Ineligibility for intensive chemotherapy should be explicitly approved by a multidisciplinary team in countries in which this process is standard of care 4. Adequate renal and hepatic functions prior to randomization: -AST and ALT <3 × ULN; for participants with leukemic organ involvement (documented by biopsy or imaging) AST and ALT <5 × ULN is permitted. -Total bilirubin 3× ULN, unless of non-hepatic origin. If bilirubin rise is due to congenital nonhemolytic hyperbilirubinemia such as Gilberts syndrome (in which case conjugated bilirubin needs to be within a clinically acceptable range and total bilirubin 3 × ULN). -eGFR (MDRD formula) 5. WBC count < 25 X 10^9/ L

Criterios de Exclusión

1. Known active leukemic involvement of the CNS
2. History of myelofibrosis
3. Cardiac disease: a. Any of the following within 6 months of randomization: myocardial infarction, uncontrolled/unstable angina, congestive heart failure (NYHA Class III or IV uncontrolled or symptomatic arrhythmias, stroke, or transient ischemic attack. b. QTcF 470 msec. Participants with a family history of Long QT syndrome are excluded. For participants with documented wide QRS interval (eg, due to a bundle branch block), alternate methods of calculating a corrected QT interval may be appropriate for eligibility determination if recommended by a consulting cardiologist and approved by the sponsor, provided there is no evidence or history of a repolarization abnormality.
4. Chronic respiratory disease requiring supplemental oxygen
5. Active infection that is uncontrolled prior to first dose of study treatment and may interfere with the study objectives or expose the patient to undue risk by participating in the trial; an infection controlled with systemic therapy is allowed.

Calendario

(Última actualización: 20/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/07/2025	07/08/2025	07/08/2025	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

Janssen Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@imim.es

933160679

Centros

Activo (28/07/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (28/07/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (14/07/2026)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Activo (10/10/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (28/10/2025)

Hospital De Jerez De La Frontera

Jerez De La Frontera

CÁDIZ

Hematology

Activo (27/10/2025)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Activo (18/09/2025)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (08/09/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (28/07/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (29/09/2025)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (21/08/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (28/07/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (24/10/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Activo (30/07/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (08/09/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (28/07/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Azacitidine betapharm 25 mg/mL powder for suspension for injection
SUSPENSION FOR INJECTION
INTRAVENOUS USE

Código ATC: L01BC07 - AZACITIDINA
Principios Activos: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Sin resultados

A Study of Bleximenib, Venetoclax and Azacitidine For Treatment of Participants With Newly Diagnosed Acute Myeloid Leukemia

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	338
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, effectiveness	NO

Information

Identifier
2024-520154-38-00 (CTIS)

Protocol Code
75276617AML3001

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

Investigated Disease
Acute Myeloid Luekemia

Scientific Title
A Phase 3 Randomized, Double-blind, Placebo-controlled, Study of Bleximenib, Venetoclax and Azacitidine for the Treatment of Participants with Newly Diagnosed Acute Myeloid Leukemia Harboring KMT2ARearrangements or NPM1Mutations who are Ineligible for Intensive Chemotherapy

Rationale

Not provided

Main Objective

To compare the efficacy of bleximenib and VEN+AZA vs VEN+AZA alone

Primary Endpoints

Dual primary endpoints: CR and OS

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Be 18 years of age (or the legal age of majority in the jurisdiction in which the study is taking place, whichever is greater) at the time of informed consent. 2. Previously untreated KMT2Ar or NPM1m AML with 10% blasts per 2022 ICC criteria. -Participants with KMT2A partial tandem duplications or amplifications are NOT eligible. - Emergency leukapheresis and/or cytoreductive therapy with hydroxyurea and/or to a total of 2 g/m2 cytarabine (cytarabine may be administered over a maximum of 5 days, not to exceed 3 doses) is permitted prior to first dose of study treatment. Note: cytoreductive therapy with cytarabine should not be given until after the screening bone marrow assessment. Leukapheresis and cytarabine must be discontinued 1 day prior to first dose of study treatment. 3. Ineligible for intensive chemotherapy based on the following criteria: 75 years of age and ineligible per physicians discretion, with ECOG performance status of 0-2 18 to <75 years of age with 1 of the following comorbidities: ECOG performance status of 2 Severe cardiac disorder (eg, congestive heart failure requiring treatment or chronic stable angina) Severe

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Exclusion criteria

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4. Chronic respiratory disease requiring supplemental oxygen
5. Active infection that is uncontrolled prior to first dose of study treatment and may interfere with the study objectives or expose the patient to undue risk by participating in the trial; an infection controlled with systemic therapy is allowed.

Calendar

(Last Update: 20/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/07/2025	07/08/2025	07/08/2025	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

Janssen Cilag International Belgium

Turnhoutseweg 30

Contact Person

CTIS Point of Contact

+31717996133

CTISadmin@its.jnj.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc de Salut Mar

Doctor Aiguader, 88 Edificio PRBB 08003 Barcelona

ceic-psmar@imim.es

933160679

Sites

Active (28/07/2025)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (28/07/2025)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (14/07/2026)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Active (10/10/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (28/10/2025)

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Hospital Universitario Marques De Valdecilla

Santander

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Hematology

Active (21/08/2026)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (28/07/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (24/10/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

Active (30/07/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (08/09/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (28/07/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

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FILM-COATED TABLET
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Active Principles: N/A

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Active Principles: N/A

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Active Principles: N/A

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FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A

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Azacitidine betapharm 25 mg/mL powder for suspension for injection
SUSPENSION FOR INJECTION
INTRAVENOUS USE

ATC code: L01BC07 - AZACITIDINA
Active Principles: N/A

Experimental

JNJ-75276617
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

No results