

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

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase III

Participantes esperados

338

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

tratamiento, eficacia

Terapia avanzada

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 $<3 \times \text{ULN}$; for participants with leukemic organ involvement (documented by biopsy or imaging) AST and ALT $<5 \times \text{ULN}$ is permitted. -Total bilirubin $3 \times \text{ULN}$, 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 $3 \times \text{ULN}$). -eGFR (MDRD formula) 5. WBC count $< 25 \times 10^9/\text{L}$

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 09/07/2025	Inicio de Ensayo 07/08/2025	Inclusión Primer Paciente 07/08/2025	Interrumpido No aportado	Reiniciado No aportado
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

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

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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)	Complejo 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

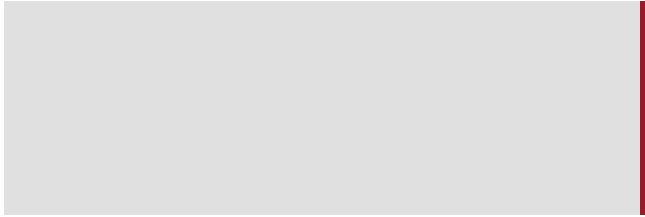
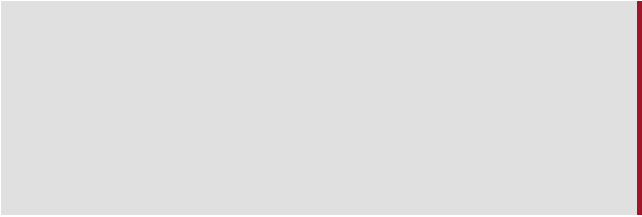
FILM-COATED TABLET

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
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase III

Expected Participants
338

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
treatment, effectiveness

Advanced therapy
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

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Calendar

(Last Update: 20/07/2026)

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

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

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Sites

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Hospital Universitario De Salamanca

Salamanca

SALAMANCA

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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

Experimental

JNJ-75276617

FILM-COATED TABLET

ORAL USE

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

JNJ-75276617

FILM-COATED TABLET

ORAL USE

Active Principles: N/A

Experimental

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

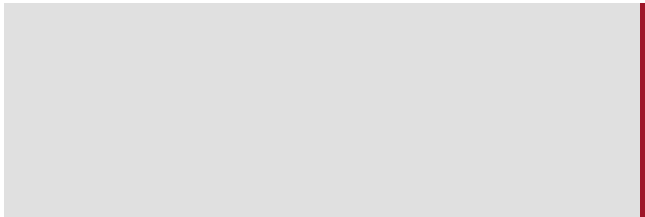
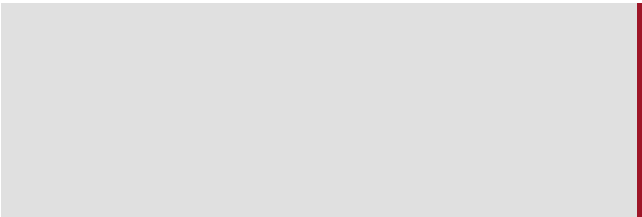
FILM-COATED TABLET

ORAL USE

ATC code: L01XX52 - VENETOCLAX

Active Principles: N/A

Experimental



No results