A Clinical Study of Cusatuzumab Plus Azacitidine in Patients With Newly Diagnosed Acute Myeloid Leukemia who are not Candidates for Intensive Chemotherapy

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	Sujetos incapaces de otorgar consentimiento	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	65
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador

2024-513283-26-00 (CTIS)

Cod. Protocolo

CULM20236

Transicionado 2019-000473-23

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Acute Myeloid Leukemia

Título Científico

A Phase 2 Study of Cusatuzumab Plus Azacitidine in Patients With Newly Diagnosed Acute Myeloid Leukemia who are not Candidates for Intensive Chemotherapy

Justificación

No aportado

Objetivo Principal

To determine the efficacy of cusatuzumab in combination with azacitidine in patients with previously untreated acute myeloid leukemia (AML) who are not eligible for intensive chemotherapy

Variables de Evaluación Primaria

Complete response (CR) rate per ELN 2017 (Dohner 2017)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To determine the below responses a) Complete response (CR) b) CR with incomplete recovery (CRi) c) CR with partial hematological revovery (CRh) d) CR without MRD (CRMRD-) e) Morphologic leukemia-free state (MLFS) f) Partial response (PR) g) Stable disease h) Relapse after CR, CRi, CRh i) Progressive Disease
To assess time to response and duration of response
To determine transfusion independence
To assess the safety profile of cusatuzumab in combination with azacitidine
To assess the pharmacokinetics of cusatuzumab alone and in combination with azacitidine
To assess the immunogenicity of cusatuzumab alone and in combination with azacitidine

Variables de Evaluación Secundaria

Rate of CRh Rate of CR + CRh Rate of Cri Overall response rate (ORR) = Rate of CR+ CRh+ CRi Rate of CR without MRD Rate of MRD negativity among participants achieving CR, CRh, CRi, or MLFS; defined as less than 1 blast or leukemic stem cell in 1,000 leukocytes (MRD level <10^-3) Time to response, defined as time from randomization in Part 1 or enrollment in Part 2 to achieving the first response of CR, CRh, or CRi; duration of response, defined as time from achieving the first response of CR, CRh, or CRi to disease relapse or death from any cause. Transfusion independence (RBC or platelets) is defined as a period of at least 56 consecutive days with no transfusion between first dose of study drug and the last dose of study drug + 30 days. Safety profile of Adverse Events (AE) and Serious Adverse Events (SAE) Pharmacokinetics Immunogenicity / anti-drug antibody testing

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

18 years of age Criterion modified per Amendment 10.1. Must sign and informed consent form (ICF) indicating that he or she (or their legally acceptable representative) understands the purpose of, and procedures required for, the study and is willing to participate in the study. Criterion modified per Amendment 1 2.1. AML according to WHO 2016 criteria and fulfilling all of the following criteria that defines those who are "not candidates for intensive chemotherapy": 75 years of age or <75 years of age with of at least one of the following comorbidities: o Eastern Cooperative Oncology Group (ECOG) Performance Status of 2 o Severe cardiac comorbidity defined as congestive heart failure or ejection fraction 50% o Severe pulmonary comorbidity defined as documented pulmonary disease with lung diffusing capacity for carbon monoxide (DLCO) 65% of expected, or forced expiratory volume in 1 second (FEV1) 65% of expected or dyspnea at rest requiring oxygen o Moderate hepatic impairment defined according to National Cancer Institute (NCI) organ dysfunction classification criteria (total bilirubin 1.5 up to 3 times upper limit of normal [ULN]) o Creatinine clearance <45 mL/ min/1.73 m² (by MDRD formula) o Comorbidity that, in the Investigator's opinion, makes the patient unsuitable for intensive chemotherapy and must be documented and approved by the Sponsor before randomization Criterion numbering modified per Amendment 1 3.1. De novo or secondary AML; Criterion modified per Amendment 1 4.1. Previously untreated AML (except: emergency leukapheresis, hydroxyurea, and /or 1 dose of cytarabine [eg, 1-2g/m^2] during the screening phase to control hyperleukocytosis. Theses treatments mst be discontinued 24 hours prior to start of study drug). Empiric all trans retinoic acid (ATRA) treatment for presumed acute promyelocytic leukemia (APL) is permited but APL mus be ruled out and ATRA mus be discontinued 24 hours prior to the start of the study drug; Criterion numbering modified per Amendment 1 5.1. Not eligible for an allogeneic hematopoietic stem cell transplantation. Criterion numbering modified per Amendment 1 6.1. ECOG Performance Status score of 0, 1 or 2. Criterion numbering modified per Amendment 1 7.1. The following clinical laboratory values at screening: Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <3 times ULN; for participants with leukemic infiltration of the liver (documented by biopsy or imaging), AST and ALT <5 times ULN is permitted Total bilirubin 3 times ULN unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin or in case of liver infiltration by AML (documented by biopsy or imaging) serum total bilirubin <5 times ULN Creatinine Clearance >30 mL/min (by MDRD formula) Criterion numbering modified per Amendment 1 8.1. A woman must be either: Not of childbearing potential: postmenopausal (>45 years of age with amenorrhea for at least 12 months); Of childbearing potential and practicing a highly effective method of birth control consistent with local regulations regarding the use of birth control methods for participants participating in the clinical study while receiving study tratment and for at least 3 months after the last dose of study treatment. A woman of childbearing potential must have a negative highly-sensitive serum (-human chorionic gonadotropin [-hCG]) or urine pregnancy test at screening. A woman fo childbearing potential must agree to not donate eggs (ova, oocytes) for the purposes of assisted reproduction during the study treatment and for 3 months after the last dose of study treatment. Note: If the childbearing potential changes after start of the study (eg, woman who is not heterosexually active becomes active, premenarchal woman experiences menarche) a woman must begin a highly effective method of birth control, as described above. Criterion modified per Amendment 1 9.1. A man who is sexually active with a woman of childbearing potential and has not had a vasectomy must agree to use a barrier method of birth control eg, either condom with spermicidal foam/gel/film/cream/suppository or partner with occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/suppository for at least 3 months after last study treatment. Must agree to not donate sperm during the study treatment and for 3 months after the last dose of study treatment. Not plan to father a chld during the study treatment and for 3 months after the last dose os study treatment.

Criterios de Exclusión

Criterion modified per Amendment 1 1.1. Acute promyelocytic leukemia
Known allergies, hypersensitivity, or intolerance to cusatuzumab or azacitidine or its excipients (ie, mannitol, an excipient of azacitidine).
Any condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (eg, compromise the well-being) or physical limitations that could prevent, limit, or confound the protocol-specified assessments.
Criterion modified per Amendment 1 12.1. Major surgery, (eg, requiring general anesthesia) within 4 weeks prior to initiation of the study.

Women who are breastfeeding.
Received a live, attenuated vaccine within 4 weeks prior to initiation of study treatment. NOTE: Investigators should ensure that all study enrollment (inclusion/exclusion) criteria have been met at screening and prior to the first dose of study intervention. If a participant's clinical status changes (including any available laboratory results or receipt of additional medical records) after screening but before the first dose of study intervention is given such that he or she no longer meets all eligibility criteria, then the participant should be excluded from participation in the study.
Leukemic involvement or clinical symptoms of leukemic involvement of the central nervous system.
Criterion modified per Amendment 1 3.1. Use of immune suppressive agents for the past 4 weeks before the first administration of cusatuzumab on Cycle 1 Day 3. For regular use of systemic corticosteroids, participants may only be included if free of systemic corticosteroids for a minimum of 5 days before the first administration of cusatuzumab. Treatment of adrenal insufficiency with physiologic replacement doses of corticosteroids are allowed.
Prior treatment with a hypomethylating agent for treatment of AML or MDS
Criterion modified per Amendment 1 5.1. Active malignancies (ie, progressing or requiring treatment in the last 24 months) other than the disease being treated under study. The only allowed exceptions are: Non-melanoma skin cancer treated within the last 24 months that is considered completely cured Adequately treated breast lobular carcinoma in situ and breast ductal carcinoma in situ Adequately treated cervical carcinoma in situ without evidence of disease History of localized breast cancer and receiving antihormonal agents, or history of localized prostate cancer (N0M0) and receiving androgen deprivation therapy Malignancy that is considered cured with minimal risk of recurrence
Criterion modified per Amendment 1 6.1. Any active systemic infection
Criterion modified per Amendment 1 7.1. A history of human immunodeficiency virus (HIV) antibody positive or tests positive for HIV at screening
Criterion modified per Amendment 1 8.1. Active hepatitis B or C infection or other clinically active liver disease Seropositive for hepatitis B: defined by a positive test for hepatitis B surface antigen [HBsAg]. Participants with resolved infection (ie, participants who are HBsAg negative with antibodies to total hepatitis B core antigen [anti-HBc] with or without the presence of hepatitis B surface antibody [anti-HBs]) must be screened using real-time polymerase chain reaction (RT-PCR) measurement of hepatitis B virus (HBV) DNA levels. Those who are RT-PCR positive will be excluded. Participants with serologic findings suggestive of HBV vaccination (antiHBs positivity as the only serologic marker) AND a known history of prior HBV vaccination, do not need to be tested for HBV DNA by RT-PCR.
Known Hepatitis C infection or positive serologic testing for Hepatitis C (anti-HCV antibody)
New York Heart Association Class IV heart failure or ongoing unstable angina

Calendario

(Última actualización: 23/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
19/08/2019	20/08/2019	14/10/2019	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
28/07/2020	No aportado	No aportado	06/03/2026	No aportado

Promotor

OncoVerity Inc. United States

12635 East Montview Boulevard

Contact Person

OncoVerity Help Desk

+35312912000

oncoverityhelpdesk@oncoverity.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

Cerrado (24/08/2021)

COMPLEJO ASISTENCIAL SON ESPASES (*)

Palma de Mallorca

BALEARES

Servicio de Hematologia

Activo (28/10/2019)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Hematologia

Cerrado (02/03/2021)

HOSPITAL QUIRÓNSALUD MADRID

Pozuelo de Alarcón

MADRID

Servicio de Hematologia y Hemoterapia

Cerrado (16/12/2020)

HOSPITAL RAMÓN Y CAJAL

Madrid

MADRID

Servicio de Hematologia

Cerrado (08/06/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematologia

Cerrado (08/10/2020)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Servicio de Hematologia

Cerrado (30/09/2020)

HOSPITAL UNIVERSITARIO REINA SOFÍA

Córdoba

CÓRDOBA

Servicio de Hematologia

Cerrado (08/09/2020)

HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

Valencia

VALENCIA

Departamento de Hematologia

Cerrado (30/09/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematologia

Activo (09/10/2019)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

servicio de hematologia

Medicamentos

AZACITIDINE

POWDER FOR SUSPENSION FOR INJECTION

SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

AZACITIDINE

POWDER FOR SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Cusatuzumab

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

A Clinical Study of Cusatuzumab Plus Azacitidine in Patients With Newly Diagnosed Acute Myeloid Leukemia who are not Candidates for Intensive Chemotherapy

State	**Type of participants**	**Age Ranges**
Finished CT	Incapable subjects of giving consent	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	65
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2024-513283-26-00 (CTIS)

Protocol Code
CULM20236

Transitioned 2019-000473-23

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

Investigated Disease
Acute Myeloid Leukemia

Scientific Title
A Phase 2 Study of Cusatuzumab Plus Azacitidine in Patients With Newly Diagnosed Acute Myeloid Leukemia who are not Candidates for Intensive Chemotherapy

Rationale

Not provided

Main Objective

To determine the efficacy of cusatuzumab in combination with azacitidine in patients with previously untreated acute myeloid leukemia (AML) who are not eligible for intensive chemotherapy

Primary Endpoints

Complete response (CR) rate per ELN 2017 (Dohner 2017)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To determine the below responses a) Complete response (CR) b) CR with incomplete recovery (CRi) c) CR with partial hematological revovery (CRh) d) CR without MRD (CRMRD-) e) Morphologic leukemia-free state (MLFS) f) Partial response (PR) g) Stable disease h) Relapse after CR, CRi, CRh i) Progressive Disease
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Secondary Endpoints

Rate of CRh Rate of CR + CRh Rate of Cri Overall response rate (ORR) = Rate of CR+ CRh+ CRi Rate of CR without MRD Rate of MRD negativity among participants achieving CR, CRh, CRi, or MLFS; defined as less than 1 blast or leukemic stem cell in 1,000 leukocytes (MRD level <10^-3) Time to response, defined as time from randomization in Part 1 or enrollment in Part 2 to achieving the first response of CR, CRh, or CRi; duration of response, defined as time from achieving the first response of CR, CRh, or CRi to disease relapse or death from any cause. Transfusion independence (RBC or platelets) is defined as a period of at least 56 consecutive days with no transfusion between first dose of study drug and the last dose of study drug + 30 days. Safety profile of Adverse Events (AE) and Serious Adverse Events (SAE) Pharmacokinetics Immunogenicity / anti-drug antibody testing

Temporary moments of secondary assessment

Not provided

Inclusion criteria

18 years of age Criterion modified per Amendment 10.1. Must sign and informed consent form (ICF) indicating that he or she (or their legally acceptable representative) understands the purpose of, and procedures required for, the study and is willing to participate in the study. Criterion modified per Amendment 1 2.1. AML according to WHO 2016 criteria and fulfilling all of the following criteria that defines those who are "not candidates for intensive chemotherapy": 75 years of age or <75 years of age with of at least one of the following comorbidities: o Eastern Cooperative Oncology Group (ECOG) Performance Status of 2 o Severe cardiac comorbidity defined as congestive heart failure or ejection fraction 50% o Severe pulmonary comorbidity defined as documented pulmonary disease with lung diffusing capacity for carbon monoxide (DLCO) 65% of expected, or forced expiratory volume in 1 second (FEV1) 65% of expected or dyspnea at rest requiring oxygen o Moderate hepatic impairment defined according to National Cancer Institute (NCI) organ dysfunction classification criteria (total bilirubin 1.5 up to 3 times upper limit of normal [ULN]) o Creatinine clearance <45 mL/ min/1.73 m² (by MDRD formula) o Comorbidity that, in the Investigator's opinion, makes the patient unsuitable for intensive chemotherapy and must be documented and approved by the Sponsor before randomization Criterion numbering modified per Amendment 1 3.1. De novo or secondary AML; Criterion modified per Amendment 1 4.1. Previously untreated AML (except: emergency leukapheresis, hydroxyurea, and /or 1 dose of cytarabine [eg, 1-2g/m^2] during the screening phase to control hyperleukocytosis. Theses treatments mst be discontinued 24 hours prior to start of study drug). Empiric all trans retinoic acid (ATRA) treatment for presumed acute promyelocytic leukemia (APL) is permited but APL mus be ruled out and ATRA mus be discontinued 24 hours prior to the start of the study drug; Criterion numbering modified per Amendment 1 5.1. Not eligible for an allogeneic hematopoietic stem cell transplantation. Criterion numbering modified per Amendment 1 6.1. ECOG Performance Status score of 0, 1 or 2. Criterion numbering modified per Amendment 1 7.1. The following clinical laboratory values at screening: Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) <3 times ULN; for participants with leukemic infiltration of the liver (documented by biopsy or imaging), AST and ALT <5 times ULN is permitted Total bilirubin 3 times ULN unless bilirubin rise is due to Gilbert's syndrome or of non-hepatic origin or in case of liver infiltration by AML (documented by biopsy or imaging) serum total bilirubin <5 times ULN Creatinine Clearance >30 mL/min (by MDRD formula) Criterion numbering modified per Amendment 1 8.1. A woman must be either: Not of childbearing potential: postmenopausal (>45 years of age with amenorrhea for at least 12 months); Of childbearing potential and practicing a highly effective method of birth control consistent with local regulations regarding the use of birth control methods for participants participating in the clinical study while receiving study tratment and for at least 3 months after the last dose of study treatment. A woman of childbearing potential must have a negative highly-sensitive serum (-human chorionic gonadotropin [-hCG]) or urine pregnancy test at screening. A woman fo childbearing potential must agree to not donate eggs (ova, oocytes) for the purposes of assisted reproduction during the study treatment and for 3 months after the last dose of study treatment. Note: If the childbearing potential changes after start of the study (eg, woman who is not heterosexually active becomes active, premenarchal woman experiences menarche) a woman must begin a highly effective method of birth control, as described above. Criterion modified per Amendment 1 9.1. A man who is sexually active with a woman of childbearing potential and has not had a vasectomy must agree to use a barrier method of birth control eg, either condom with spermicidal foam/gel/film/cream/suppository or partner with occlusive cap (diaphragm or cervical/vault caps) with spermicidal foam/gel/film/cream/suppository for at least 3 months after last study treatment. Must agree to not donate sperm during the study treatment and for 3 months after the last dose of study treatment. Not plan to father a chld during the study treatment and for 3 months after the last dose os study treatment.

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Criterion modified per Amendment 1 12.1. Major surgery, (eg, requiring general anesthesia) within 4 weeks prior to initiation of the study.

Women who are breastfeeding.
Received a live, attenuated vaccine within 4 weeks prior to initiation of study treatment. NOTE: Investigators should ensure that all study enrollment (inclusion/exclusion) criteria have been met at screening and prior to the first dose of study intervention. If a participant's clinical status changes (including any available laboratory results or receipt of additional medical records) after screening but before the first dose of study intervention is given such that he or she no longer meets all eligibility criteria, then the participant should be excluded from participation in the study.
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Known Hepatitis C infection or positive serologic testing for Hepatitis C (anti-HCV antibody)
New York Heart Association Class IV heart failure or ongoing unstable angina

Calendar

(Last Update: 23/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
19/08/2019	20/08/2019	14/10/2019	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
28/07/2020	Not aported	Not aported	06/03/2026	Not aported

Sponsor

OncoVerity Inc. United States

12635 East Montview Boulevard

Contact Person

OncoVerity Help Desk

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oncoverityhelpdesk@oncoverity.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Sites

Closed (24/08/2021)

COMPLEJO ASISTENCIAL SON ESPASES (*)

Palma de Mallorca

BALEARES

Servicio de Hematologia

Active (28/10/2019)

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Córdoba

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HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE

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VALENCIA

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Closed (30/09/2020)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematologia

Active (09/10/2019)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

servicio de hematologia

Medication

AZACITIDINE

POWDER FOR SUSPENSION FOR INJECTION

SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

AZACITIDINE

POWDER FOR SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

Cusatuzumab

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Active Principles: N/A

Orphan

Experimental

No results