A Randomized Study Comparing Blinatumomab Alternating With Low-intensity Chemotherapy Versus Standard of Care Chemotherapy for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia with Safety Run-in (Golden Gate Study)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	134
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-503640-14-00 (CTIS)

Cod. Protocolo
20190360

Transicionado 2019-004304-36

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

Enfermedad investigada
Newly diagnosed Philadelphia-negative B-cell precursor Acute Lymphoblastic Leukemia in older adults

Título Científico
Phase 3 Randomized, Controlled Study of Blinatumomab Alternating With Low-intensity Chemotherapy Versus

Standard of Care for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia With Safety Run-in (Golden Gate Study)

Justificación

No aportado

Objetivo Principal

Safety Run In (SRI): To evaluate the safety and tolerability of blinatumomab alternating with low-intensity chemotherapy Phase 3 (Ph3): To compare event-free survival (EFS) of subjects receiving blinatumomab alternating with low-intensity chemotherapy to EFS of subjects receiving standard of care (SOC) chemotherapy
Ph3: To compare overall survival (OS) of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy

Variables de Evaluación Primaria

SRI: Treatment-emergent adverse events, treatment-related adverse events, and adverse events of interest
Ph3: EFS: time from randomization until treatment failure, relapse, or death from any cause, whichever is earlier. Subjects without an event will be censored at their last evaluable disease assessment date.
Ph3: OS: time from randomization until death due to any cause. Subjects alive will be censored at the date last known to be alive.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

SRI: To evaluate efficacy endpoints of blinatumomab alternating with low-intensity chemotherapy
SRI: To characterize the pharmacokinetics (PK) of blinatumomab alternating with low-intensity chemotherapy
Ph3: To compare patient-reported fatigues with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare patient-reported pain with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare additional patient-reported outcomes (PROs) and global health status as measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQC30)
Ph3: To compare other efficacy endpoints of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare the safety of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To characterize relapses by cluster of differentiation (CD)19 expression, lineage switch and relapse localization in both treatment arms.
Ph3: To evaluate non-relapse mortality in both treatment arms
Ph3: To evaluate the proportion of allogeneic and autologous HSCT in continuous first CR after receiving blinatumomab alternating with low-intensity chemotherapy compared to SOC chemotherapy

Ph3: To evaluate non-relapse mortality following autologous and allogeneic HSCT in both treatment arms
Ph3: To evaluate relapse rate following autologous and allogeneic HSCT in both treatment arms
Ph3: To compare patient-reported fatigues with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare patient-reported pain with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare additional PROs and global health status as measured by the EORTC QLQ-C30
Ph3: To evaluate the PK of blinatumomab

Variables de Evaluación Secundaria

SRI: Complete remission (CR) by the end of the initial disease assessment period SRI: Minimal residual disease (MRD) response < 10-4 by the end of the initial disease assessment period SRI: Relapse-free survival (RFS): in subjects who achieve CR, the time from first achievement of this response until date of the first relapse including hematologic relapse, extramedullary relapse, or death due to any cause, whichever occurs first. Subjects without an event will be censored at their last evaluable disease assessment date. SRI: MRD RFS in subjects who achieve CR with MRD response, the time from first achievement of this response until date of the first relapse including molecular relapse, hematologic relapse, and/or extramedullary relapse, or death due to any cause, whichever occurs first. Molecular relapse will be defined 2 ways: MRD 10-3 and MRD 10-4. Subjects without an event will be censored at their last evaluable disease assessment date. SRI: PK parameters for blinatumomab including, but not limited to, steady state concentration (Css) and clearance (CL) Ph3: Change from baseline to end of the initial disease assessment period in fatigue score measured by Patient-Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form 7a Ph3: Change from baseline to end of the initial disease assessment period in pain score measured by Brief Pain Inventory Short Form (BPI-SF); Item 3: pain at its worst in the last 24 hours Ph3: Change from baseline to end of the initial disease assessment period in global health status measured by the QLQ-C30 global health status quality of life scale Ph3: Change from baseline to end of the initial disease assessment period in physical function measured by the QLQ-C30 functional scale Ph3: Change from baseline to end of the initial disease assessment period in nausea/vomiting measured by the QLQ-C30 symptom scale Ph3: CR by the end of the initial disease assessment period Ph3: MRD response < 10-4 by the end of the initial disease assessment period Ph3: RFS: in subjects who achieve CR, the time from first achievement of this response until date of the first relapse including hematologic relapse, extramedullary relapse, or death due to any cause, whichever occurs first. Subjects without an event will be censored at their last evaluable disease assessment date. Ph3: MRD RFS in subjects who achieve CR with MRD response, the time from first achievement of this response until date of the first relapse including molecular relapse, hematologic relapse, and/or extramedullary relapse, or death due to any cause, whichever occurs first. Molecular relapse will be defined 2 ways: MRD 10-3 and MRD 10-4. Subjects without an event will be censored at their last evaluable disease assessment date. Ph3: MRD level over time Ph3: treatment-emergent adverse events, treatment related adverse events, and adverse events of interest Ph3: CD19 positive relapse and CD19 negative relapse identified by flow cytometry or immunocytochemistry for bone marrow (mandatory) Ph3: CD19 positive relapse and CD19 negative relapse identified by flow cytometry or immunohistochemistry for cerebrospinal fluid (mandatory) Ph3: CD19 positive relapse and CD19 negative relapse for extramedullary sites other than cerebrospinal fluid (optional - if data is available) Ph3: Lineage switch to acute myeloid leukemia (AML) Ph3: Localization of relapse by clinical assessment Ph3: Mortality in CR Ph3: Autologous and allogeneic HSCT in continuous first CR* Ph3: Mortality in CR after autologous and allogeneic HSCT* Ph3: Relapse after autologous and allogeneic HSCT Ph3: Time to deterioration and time to improvements for fatigue score measured by PROMIS Fatigue Short Form 7a Ph3: Time to deterioration and time to improvements for pain score measured by BPI-SF; Item 3: pain at its worst in the last 24 hours Ph3: Change from baseline in all other subscales of QLQ-C30 (role, cognitive, emotional, and social scales; pain and fatigue scales; single items: dyspnea, loss of appetite, insomnia, constipation, diarrhea, and perceived financial impact) Ph3: Time to deterioration and time to improvements for global health status, physical function, and nausea/vomiting scales. Ph3: Css and CL

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subject has provided informed consent prior to initiation of any study specific activities/procedures OR Where permitted by local law, subjects legally acceptable representative has provided informed consent prior to any study-specific activities/procedures being initiated when the subject has any kind of condition that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent. Age 55 years at the time of informed consent OR Age 40 to < 55 years of age if at least 1 of the following comorbidities at the time of informed consent: - history of grades 3 and 4 pancreatitis - diabetes mellitus with end-organ damage - severe liver disease such as cirrhosis stage 2 with portal hypertension or history of esophageal variceal bleeding and aspartate aminotransferase (AST)/alanine aminotransferase (ALT) > 10 x upper limit of normal (ULN) (liver cirrhosis must be confirmed by biopsy) - body mass index (BMI) 40 combined with relevant comorbidities such as metabolic syndrome - Any further combination of documented severe comorbidities that the investigator judges to be incompatible with administering an intensive pediatric-based, adult adapted standard chemotherapy regimen but still compatible with the suggested protocol for older subjects in both the experimental and the SOC arm. The subject history needs to be reviewed by the medical monitor during screening to determine enrollment acceptability based on a standard list with types of comorbidities allowed. Subjects with newly diagnosed Philadelphia (Ph)-negative B-cell precursor acute lymphoblastic leukemia (ALL) per WHO criteria Eastern Cooperative Oncology Group (ECOG) performance status 2, higher ECOG score allowed if due to underlying leukemia. All subjects must have adequate organ function as defined below: - renal: estimated glomerular filtration rate based on Modification of Diet in Renal Disease (MDRD) calculation 50 mL/min/1.73 m2 - liver function: total bilirubin 2x upper limit of normal (ULN; unless Gilberts Disease or if liver involvement with leukemia); exception for subjects 40 to < 55 years of age if comorbidity is per inclusion 102: severe liver disease such as cirrhosis stage 2 with portal hypertension or history of esophageal variceal bleeding and AST/ALT >10 x ULN (liver cirrhosis must be confirmed by biopsy) - cardiac: left ventricular ejection fraction (LVEF) 50% and no clinically significant, uncontrolled, or active cardiovascular disease (eg, myocardial infarction or stroke within 3 months). Consult with medical monitor as needed.

Criterios de Exclusión

Active CNS leukemia (i.e, CNS 3 leukemia, confirmed by lumbar puncture) not resolved with IT chemotherapy during screening
History of other malignancy within the past 3 years, with the following exceptions: - Malignancy treated with curative intent and with no known active disease present for 3 years before enrollment and felt to be at low risk for recurrence by the treating physician. - Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease. - Adequately treated cervical carcinoma in situ without evidence of disease. - Adequately treated breast ductal carcinoma in situ without evidence of disease. - Prostatic intraepithelial neoplasia without evidence of prostate cancer. - Adequately treated urothelial papillary noninvasive carcinoma or carcinoma in situ.
History or presence of clinically relevant CNS pathology or eventsuch as epilepsy, childhood or adult seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's diease, cerebellar disease, organic brain syndrome, or psychiatric conditions that preclude the use of high dose of corticosteroids. Consult with medical monitor as needed.
Current autoimmune disease or history of autoimmune disease with potential CNS involvement
Known infection with human immunodeficiency virus (HIV)
Known infection with chronic or active hepatitis B (eg, hepatitis b surface [HBs] antigen reactive or quantifiable hepatitis b virus [HBV] viral load) or hepatitis C virus (HCV) (eg, HCV RNA [qualitative] is detected). Active hepatitis B and C based on the following results: - Positive for hepatitis B surface antigen (HepBsAg) (indicative of chronic hepatitis B or recent acute hepatitis B) - Negative HepBsAg and positive for hepatitis B core antibody: negative HBV DNA by PCR result is necessary to enroll. - Positive Hepatitis C virus antibody (HepCAb): negative hepatitis C virus RNA by PCR result is necessary to enroll.
Subject with symptoms and/or clinical signs and/or radiographic and/or sonographic signs that indicate an acute or

uncontrolled chronic infection.
Cancer chemotherapy for this newly diagnosed B cell ALL before the start of protocol-required therapy with the exception of IT chemotherapy or pre-phase chemotherapy. Radiation to a spot lesion such as chloroma or lytic lesion of bone or vertebrae for pain or vertebral stabilization is allowed.
Currently receiving treatment in another investigational device or drug study, or less than 30 days since ending treatment on another investigational device or drug study(ies). Other investigational procedures while participating in this study are excluded.

Calendario

(Última actualización: 09/02/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/11/2020	17/02/2022	29/05/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
20/07/2022	No aportado	No aportado	24/01/2023	No aportado

Promotor

Amgen Inc. United States

1 Amgen Center Drive

Contact Person

Medical Information

+441895525000

euctlegalrep@amgen.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

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915867007

Centros

Cerrado (11/01/2021)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital General Universitario Reina Sofia

Cordoba

CÓRDOBA

Servicio de Hematologia

Cerrado (24/01/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Servicio de Hematologia

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematologia

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematologia

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Servicio de Hematologia

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Servicio de Hematologia

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Servicio de Hematologia Clinica

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

Institut Catala D´oncologia

Badalona

BARCELONA

Servicio de Hematologia Clinica

Medicamentos

MERCAPTOPURINE
TABLETS
ORAL USE

-

Principios Activos: N/A

Experimental

METHOTREXATE SODIUM
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

PREDNISONE
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

ASPARAGINASE
SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

CRISANTASPASE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

MERCAPTOPURINE
TABLETS
ORAL USE

-

Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

METHOTREXATE SODIUM
TABLET
ORAL USE

DOXORUBICIN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

-

Principios Activos: N/A

Experimental

DEXAMETHASONE

TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE

POWDER FOR SOLUTION FOR INJECTION

INTRAVENOUS

-

Principios Activos: N/A

Experimental

METHOTREXATE SODIUM

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

METHOTREXATE SODIUM

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

BLINATUMOMAB

SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Principios Activos: N/A

Huérfano

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

BLINATUMOMAB

SOLUTION FOR INFUSION

INTRAVENOUS USE

PEGASPARGASE

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS USE

-

Principios Activos: N/A

Huérfano **Experimental**

-

Principios Activos: N/A

Experimental

Tiene resultados

A Randomized Study Comparing Blinatumomab Alternating With Low-intensity Chemotherapy Versus Standard of Care Chemotherapy for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia with Safety Run-in (Golden Gate Study)

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	134
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-503640-14-00 (CTIS)

Protocol Code
20190360

Transitioned 2019-004304-36

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

Investigated Disease
Newly diagnosed Philadelphia-negative B-cell precursor Acute Lymphoblastic Leukemia in older adults

Scientific Title
Phase 3 Randomized, Controlled Study of Blinatumomab Alternating With Low-intensity Chemotherapy Versus

Standard of Care for Older Adults With Newly Diagnosed Philadelphia-negative B-cell Precursor Acute Lymphoblastic Leukemia With Safety Run-in (Golden Gate Study)

Rationale

Not provided

Main Objective

Safety Run In (SRI): To evaluate the safety and tolerability of blinatumomab alternating with low-intensity chemotherapy Phase 3 (Ph3): To compare event-free survival (EFS) of subjects receiving blinatumomab alternating with low-intensity chemotherapy to EFS of subjects receiving standard of care (SOC) chemotherapy
Ph3: To compare overall survival (OS) of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy

Primary Endpoints

SRI: Treatment-emergent adverse events, treatment-related adverse events, and adverse events of interest
Ph3: EFS: time from randomization until treatment failure, relapse, or death from any cause, whichever is earlier. Subjects without an event will be censored at their last evaluable disease assessment date.
Ph3: OS: time from randomization until death due to any cause. Subjects alive will be censored at the date last known to be alive.

Temporary moments of secondary assessment

Not provided

Secondary Objective

SRI: To evaluate efficacy endpoints of blinatumomab alternating with low-intensity chemotherapy
SRI: To characterize the pharmacokinetics (PK) of blinatumomab alternating with low-intensity chemotherapy
Ph3: To compare patient-reported fatigues with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare patient-reported pain with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare additional patient-reported outcomes (PROs) and global health status as measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQC30)
Ph3: To compare other efficacy endpoints of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare the safety of blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To characterize relapses by cluster of differentiation (CD)19 expression, lineage switch and relapse localization in both treatment arms.
Ph3: To evaluate non-relapse mortality in both treatment arms
Ph3: To evaluate the proportion of allogeneic and autologous HSCT in continuous first CR after receiving blinatumomab alternating with low-intensity chemotherapy compared to SOC chemotherapy

Ph3: To evaluate non-relapse mortality following autologous and allogeneic HSCT in both treatment arms
Ph3: To evaluate relapse rate following autologous and allogeneic HSCT in both treatment arms
Ph3: To compare patient-reported fatigues with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare patient-reported pain with blinatumomab alternating with low-intensity chemotherapy to SOC chemotherapy
Ph3: To compare additional PROs and global health status as measured by the EORTC QLQ-C30
Ph3: To evaluate the PK of blinatumomab

Secondary Endpoints

SRI: Complete remission (CR) by the end of the initial disease assessment period SRI: Minimal residual disease (MRD) response < 10-4 by the end of the initial disease assessment period SRI: Relapse-free survival (RFS): in subjects who achieve CR, the time from first achievement of this response until date of the first relapse including hematologic relapse, extramedullary relapse, or death due to any cause, whichever occurs first. Subjects without an event will be censored at their last evaluable disease assessment date. SRI: MRD RFS in subjects who achieve CR with MRD response, the time from first achievement of this response until date of the first relapse including molecular relapse, hematologic relapse, and/or extramedullary relapse, or death due to any cause, whichever occurs first. Molecular relapse will be defined 2 ways: MRD 10-3 and MRD 10-4. Subjects without an event will be censored at their last evaluable disease assessment date. SRI: PK parameters for blinatumomab including, but not limited to, steady state concentration (Css) and clearance (CL) Ph3: Change from baseline to end of the initial disease assessment period in fatigue score measured by Patient-Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form 7a Ph3: Change from baseline to end of the initial disease assessment period in pain score measured by Brief Pain Inventory Short Form (BPI-SF); Item 3: pain at its worst in the last 24 hours Ph3: Change from baseline to end of the initial disease assessment period in global health status measured by the QLQ-C30 global health status quality of life scale Ph3: Change from baseline to end of the initial disease assessment period in physical function measured by the QLQ-C30 functional scale Ph3: Change from baseline to end of the initial disease assessment period in nausea/vomiting measured by the QLQ-C30 symptom scale Ph3: CR by the end of the initial disease assessment period Ph3: MRD response < 10-4 by the end of the initial disease assessment period Ph3: RFS: in subjects who achieve CR, the time from first achievement of this response until date of the first relapse including hematologic relapse, extramedullary relapse, or death due to any cause, whichever occurs first. Subjects without an event will be censored at their last evaluable disease assessment date. Ph3: MRD RFS in subjects who achieve CR with MRD response, the time from first achievement of this response until date of the first relapse including molecular relapse, hematologic relapse, and/or extramedullary relapse, or death due to any cause, whichever occurs first. Molecular relapse will be defined 2 ways: MRD 10-3 and MRD 10-4. Subjects without an event will be censored at their last evaluable disease assessment date. Ph3: MRD level over time Ph3: treatment-emergent adverse events, treatment related adverse events, and adverse events of interest Ph3: CD19 positive relapse and CD19 negative relapse identified by flow cytometry or immunocytochemistry for bone marrow (mandatory) Ph3: CD19 positive relapse and CD19 negative relapse identified by flow cytometry or immunohistochemistry for cerebrospinal fluid (mandatory) Ph3: CD19 positive relapse and CD19 negative relapse for extramedullary sites other than cerebrospinal fluid (optional - if data is available) Ph3: Lineage switch to acute myeloid leukemia (AML) Ph3: Localization of relapse by clinical assessment Ph3: Mortality in CR Ph3: Autologous and allogeneic HSCT in continuous first CR* Ph3: Mortality in CR after autologous and allogeneic HSCT* Ph3: Relapse after autologous and allogeneic HSCT Ph3: Time to deterioration and time to improvements for fatigue score measured by PROMIS Fatigue Short Form 7a Ph3: Time to deterioration and time to improvements for pain score measured by BPI-SF; Item 3: pain at its worst in the last 24 hours Ph3: Change from baseline in all other subscales of QLQ-C30 (role, cognitive, emotional, and social scales; pain and fatigue scales; single items: dyspnea, loss of appetite, insomnia, constipation, diarrhea, and perceived financial impact) Ph3: Time to deterioration and time to improvements for global health status, physical function, and nausea/vomiting scales. Ph3: Css and CL

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subject has provided informed consent prior to initiation of any study specific activities/procedures OR Where permitted by local law, subjects legally acceptable representative has provided informed consent prior to any study-specific activities/procedures being initiated when the subject has any kind of condition that, in the opinion of the investigator, may compromise the ability of the subject to give written informed consent. Age 55 years at the time of informed consent OR Age 40 to < 55 years of age if at least 1 of the following comorbidities at the time of informed consent: - history of grades 3 and 4 pancreatitis - diabetes mellitus with end-organ damage - severe liver disease such as cirrhosis stage 2 with portal hypertension or history of esophageal variceal bleeding and aspartate aminotransferase (AST)/alanine aminotransferase (ALT) > 10 x upper limit of normal (ULN) (liver cirrhosis must be confirmed by biopsy) - body mass index (BMI) 40 combined with relevant comorbidities such as metabolic syndrome - Any further combination of documented severe comorbidities that the investigator judges to be incompatible with administering an intensive pediatric-based, adult adapted standard chemotherapy regimen but still compatible with the suggested protocol for older subjects in both the experimental and the SOC arm. The subject history needs to be reviewed by the medical monitor during screening to determine enrollment acceptability based on a standard list with types of comorbidities allowed. Subjects with newly diagnosed Philadelphia (Ph)-negative B-cell precursor acute lymphoblastic leukemia (ALL) per WHO criteria Eastern Cooperative Oncology Group (ECOG) performance status 2, higher ECOG score allowed if due to underlying leukemia. All subjects must have adequate organ function as defined below: - renal: estimated glomerular filtration rate based on Modification of Diet in Renal Disease (MDRD) calculation 50 mL/min/1.73 m2 - liver function: total bilirubin 2x upper limit of normal (ULN; unless Gilberts Disease or if liver involvement with leukemia); exception for subjects 40 to < 55 years of age if comorbidity is per inclusion 102: severe liver disease such as cirrhosis stage 2 with portal hypertension or history of esophageal variceal bleeding and AST/ALT >10 x ULN (liver cirrhosis must be confirmed by biopsy) - cardiac: left ventricular ejection fraction (LVEF) 50% and no clinically significant, uncontrolled, or active cardiovascular disease (eg, myocardial infarction or stroke within 3 months). Consult with medical monitor as needed.

Exclusion criteria

Active CNS leukemia (i.e, CNS 3 leukemia, confirmed by lumbar puncture) not resolved with IT chemotherapy during screening
History of other malignancy within the past 3 years, with the following exceptions: - Malignancy treated with curative intent and with no known active disease present for 3 years before enrollment and felt to be at low risk for recurrence by the treating physician. - Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease. - Adequately treated cervical carcinoma in situ without evidence of disease. - Adequately treated breast ductal carcinoma in situ without evidence of disease. - Prostatic intraepithelial neoplasia without evidence of prostate cancer. - Adequately treated urothelial papillary noninvasive carcinoma or carcinoma in situ.
History or presence of clinically relevant CNS pathology or eventsuch as epilepsy, childhood or adult seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's diease, cerebellar disease, organic brain syndrome, or psychiatric conditions that preclude the use of high dose of corticosteroids. Consult with medical monitor as needed.
Current autoimmune disease or history of autoimmune disease with potential CNS involvement
Known infection with human immunodeficiency virus (HIV)
Known infection with chronic or active hepatitis B (eg, hepatitis b surface [HBs] antigen reactive or quantifiable hepatitis b virus [HBV] viral load) or hepatitis C virus (HCV) (eg, HCV RNA [qualitative] is detected). Active hepatitis B and C based on the following results: - Positive for hepatitis B surface antigen (HepBsAg) (indicative of chronic hepatitis B or recent acute hepatitis B) - Negative HepBsAg and positive for hepatitis B core antibody: negative HBV DNA by PCR result is necessary to enroll. - Positive Hepatitis C virus antibody (HepCAb): negative hepatitis C virus RNA by PCR result is necessary to enroll.
Subject with symptoms and/or clinical signs and/or radiographic and/or sonographic signs that indicate an acute or

uncontrolled chronic infection.
Cancer chemotherapy for this newly diagnosed B cell ALL before the start of protocol-required therapy with the exception of IT chemotherapy or pre-phase chemotherapy. Radiation to a spot lesion such as chloroma or lytic lesion of bone or vertebrae for pain or vertebral stabilization is allowed.
Currently receiving treatment in another investigational device or drug study, or less than 30 days since ending treatment on another investigational device or drug study(ies). Other investigational procedures while participating in this study are excluded.

Calendar

(Last Update: 09/02/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/11/2020	17/02/2022	29/05/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
20/07/2022	Not aported	Not aported	24/01/2023	Not aported

Sponsor

Amgen Inc. United States

1 Amgen Center Drive

Contact Person

Medical Information

+441895525000

euctlegalrep@amgen.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

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915867007

Sites

Closed (11/01/2021)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Hematología

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

Hospital General Universitario Reina Sofia

Cordoba

CÓRDOBA

Servicio de Hematologia

Closed (24/01/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Servicio de Hematologia

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Servicio de Hematologia

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematologia

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Servicio de Hematologia

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Servicio de Hematologia

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Servicio de Hematologia

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Servicio de Hematologia Clinica

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

Institut Catala D´oncologia

Badalona

BARCELONA

Servicio de Hematologia Clinica

Medication

MERCAPTOPURINE
TABLETS
ORAL USE

-

Active Principles: N/A

Experimental

METHOTREXATE SODIUM
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

PREDNISONE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

ASPARAGINASE
SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

CRISANTASPASE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

MERCAPTOPURINE
TABLETS
ORAL USE

-

Active Principles: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

METHOTREXATE SODIUM
TABLET
ORAL USE

DOXORUBICIN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Active Principles: N/A

Experimental

-

Active Principles: N/A

Experimental

DEXAMETHASONE

TABLET

ORAL USE

-

Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE

POWDER FOR SOLUTION FOR INJECTION

INTRAVENOUS

-

Active Principles: N/A

Experimental

METHOTREXATE SODIUM

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

METHOTREXATE SODIUM

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

BLINATUMOMAB

SOLUTION FOR INFUSION

INTRAVENOUS USE

-

Active Principles: N/A

Orphan

Experimental

DEXAMETHASONE

SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

BLINATUMOMAB

SOLUTION FOR INFUSION

INTRAVENOUS USE

PEGASPARGASE

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS USE

-

Active Principles: N/A

Orphan **Experimental**

-

Active Principles: N/A

Experimental

Has results