A Phase 2 Superiority Study with InO Monotherapy vs ALLR3 for Induction Treatment of Childhood HR or VHR First Relapse BCP ALL

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	9
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, farmacocinética, farmacodinamica, farmacogenómica	NO

Información

Identificador

2023-509810-13-00 (CTIS)

Cod. Protocolo

B1931036

Transicionado 2022-000186-40

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Acute Lymphoblastic Leukemia (ALL)

Título Científico

B1931036 - A PROSPECTIVE, RANDOMIZED, OPEN-LABEL PHASE 2 STUDY TO EVALUATE THE SUPERIORITY OF INOTUZUMAB OZOGAMICIN MONOTHERAPY VERSUS ALLR3 FOR INDUCTION TREATMENT OF CHILDHOOD HIGH- RISK OR VERY HIGH-RISK FIRST RELAPSE B-CELL PRECURSOR

ACUTE LYMPHOBLASTIC LEUKAEMIA

Justificación

No aportado

Objetivo Principal

To demonstrate the superiority of InO monotherapy vs ALLR3induction in paediatric participants between 1 and <18 years with HR or VHR first bone marrow relapse CD22-positive BCP ALL

Variables de Evaluación Primaria

Minimal residual disease (MRD)-negative, CR/CRp/CRi (per investigator assessment) at the end of induction therapy (MRD negativity is assessed by central lab and defined as leukemic blasts <1x10-4 by real time quantitative polymerase chain reaction (RQ-PCR) [with reflex to FC result if MRD is non-evaluable by RQ-PCR]).

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the long-term efficacy of InO monotherapy vs ALLR3 regimen with respect to event-free survival (EFS).
To evaluate the long-term efficacy of InO monotherapy vs ALLR3 regimen with respect to: Duration of response (DOR) Hematopoietic stem cell transplant (HSCT) rate Chimeric antigen receptor (CAR) T-cell therapy rate Overall survival (OS)
To evaluate the safety and tolerability of InO monotherapy vs ALLR3 induction
To evaluate the pharmacokinetics (PK) of InO

Variables de Evaluación Secundaria

EFS, defined as the time from randomization until objective progression, relapse from CR/CRp/CRi, based on investigator assessment per response criteria, failure to achieve CR/CRp/CRi by the end of induction, MRD persistence prior to HSCT, second malignancy, or death due to any cause.
DOR, defined as time from date of first documented response (CR/CRp/CRi) to the date of first documented objective progression, relapse from CR/CRp/CRi as determined by investigator assessment per modified NCCN response criteria, MRD persistence prior to HSCT, or death due to any cause, whichever occurs first.
HSCT (and CAR T-cell therapy) rate, defined as the number and percentage of participants being transplanted and those receiving CAR Tcell therapy after treatment with InO or ALLR3.
OS, defined as the time from the date of randomization to the date of death due to any cause.
Incidence and severity of AEs graded per NCI CTCAE v4.03.
Cmax and Ctrough

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Male or female participants between 1 and less than 18 years of age. Type of Participant and Disease Characteristics: Morphologically confirmed diagnosis of first relapse HR BCP ALL or VHR BCP ALL; HR first relapse is defined as: i. relapse occurring within 18 to 30 months of original diagnosis of ALL or within 6 months of completion of primary therapy, and ii. lacking any identified very high-risk genetic abnormalities at original diagnosis or at relapse (Groeneveld-Krentz et al, 2019) (ie, KMT2A::AFF1 fusion [t(4;11)(q21;q23)], TCF3-HLF fusion [t(17;19)(q22;p13)], TCF3- PBX1 fusion [t(1;19)(q23;p13.3)], hypodiploidy [<40 chromosomes] or masked low hypodiploidy (Molina et al, 2021), TP53 alteration). VHR is defined as: i. relapse within 18 months of original diagnosis of ALL and/or ii. with any of the following genetic abnormalities at original diagnosis or at relapse (Groeneveld-Krentz et al, 2019) (ie, KMT2A::AFF1 fusion [t(4;11)(q21;q23)], TCF3-HLF fusion [t(17;19)(q22;p13)], TCF3-PBX1 fusion [t(1;19)(q23;p13.3)], hypodiploidy [<40 chromosomes] or masked low hypodiploidy (Molina et al, 2021), TP53 alteration). CD22-positive ALL as defined by local institution Bone marrow involvement of 5% leukemic blasts (M2 status). Other Inclusion Criteria: Adequate serum chemistry parameters: An estimated glomerular filtration rate (eGFR) in participants 1 to less than 2 years of age, or estimated creatinine clearance (eCrCl) in those 2 to less than 18 years of age, 30 mL/min using the recommended formula Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 5 × institutional ULN at the time of randomization or precytoreduction/ general anesthesia; Total bilirubin 1.5 × institutional ULN unless the participant has documented Gilbert's syndrome; Prior history of thrombosis during corticosteroid use and/or asparaginase are eligible provided the participant receives anticoagulant prophylaxis per institutional guidelines. Cardiac shortening fraction 30% by echocardiogram or ejection fraction > 50% by MUGA.

Criterios de Exclusión

Any history of: Prior or ongoing hepatic SOS or prior liver failure [defined as severe acute liver injury with encephalopathy and impaired synthetic function (INR of 1.5)]; Prior allo-HSCT or CAR T-cell therapy; Isolated extramedullary leukemia; Philadelphia-chromosome positive ALL, ie. BCR-ABL/t(9;22) present; Presence of Grade 3 or Grade 4 peripheral neuropathy as defined in the Delphi consensus of acute toxic effects for childhood ALL; Hypersensitivity to the active ingredient of InO or any of its excipients; Hypersensitivity/allergy to both PEG-ASP and Erwinia-ASP; Intolerance to any of the ALLR3 agents (mitoxantrone, vincristine, dexamethasone, asparaginase); Grade 3 or Grade 4 pancreatitis due to any cause, as defined by CTCAE v4.03; Grade 3 or Grade 4 allergic reaction to a monoclonal antibody; Participants not fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy, defined as resolution of all such non-hematologic toxicities to Grade 2 per the NCI CTCAE v 4.03 prior to randomization, with the exception of the laboratory abnormalities as defined by other inclusion/exclusion criteria; Down syndrome; Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study; Charcot-Marie-Tooth disease. Prior/Concomitant therapy with: A calicheamicin-conjugated antibody (eg, InO or gemtuzumab ozogamicin) or prior therapy with a CD22-targeted therapy (immunotoxin or CAR T-cell therapy); Cytotoxic therapy within 7 days prior to enrollment, with the exception of hydroxyurea and corticosteroids, which are permitted prior to initiating study intervention. Participants may have received intrathecal chemotherapy at any time prior to study entry. NOTE: No waiting period is required for participants who relapse while receiving first-line maintenance chemotherapy. Any radiation therapy within 28 days prior to enrollment; The last dose of granulocyte colony-stimulating factor (ie, Neupogen or equivalent) administered within 7 days prior to study enrollment and/or the last dose of pegfilgrastim (Neulasta®) given within 14 days prior to enrollment; Less than 3 half-lives elapsed after the last dose of a mAb (eg, rituximab=66 days, epratuzumab=69 days). Participants must not have received blinatumomab within 4 weeks before study enrollment; Current use of any prohibited concomitant medication(s) or participants unwilling/unable to

use a permitted concomitant medication(s). Refer to Section 6.8,, Concomitant Therapy. Any vaccination with live viral vaccines within 2 weeks of the start of study therapy. Administration of an IP (eg, drug or vaccine) concurrent with study intervention or within 30 days (or as determined by the local requirement) or 5 half-lives preceding the first dose of study intervention used in this study (whichever is longer). A participant may be eligible if they are in the follow-up phase of an investigational study if they meet the criterion for time elapsed from previous administration of IP. Cases must be discussed with sponsor's medical monitor to judge eligibility. Diagnostic Assessments: Serum or urine pregnancy test positive at screening. Baseline 12 lead ECG that demonstrates clinically relevant abnormalities that may affect participant safety or interpretation of study results (eg, QTcF interval >470 msec, complete LBBB, signs of an acute or indeterminate age myocardial infarction, STT interval changes suggestive of myocardial ischemia, second- or thirddegree AV block, or serious bradyarrhythmias or tachyarrhythmias). If QTcF >470 msec, the ECG should be repeated 2 more times the average of the 3 QTcF values should be used to determine the participants eligibility. Computer interpreted ECGs should be overread locally by a physician experienced in reading ECGs before excluding participants. Participants with active infection, including (but not limited to) HBV, HCV, and known HIV or AIDS-related illness. HIV infection with CD4+ count <200/mm3 and viral load of >400 copies/mm3. Participants with stable well-controlled HIV infection may be eligible after consultation with the sponsor. HBV Participants with a positive HBsAg (ie, either acute or chronic active hepatitis) are excluded. Participants with HBV antibody positivity indicating immunity, either due to vaccination or prior natural infection, are eligible. Participants with positive anti-HBcAb but negative HBsAg and anti- HBsAb profile, depending on clinical circumstances, may be eligible. Discussion with the sponsor is indicated. HCV Participants with active HCV as determined by viral load.

Calendario

(Última actualización: 17/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/12/2022	16/05/2023	20/06/2023	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

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

+18007181021

ClinicalTrials.gov_Inquiries@pfizer.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Fundacio Sant Joan de Deu

Santa Rosa, 39-57, 3a planta 08950 Esplugues de Llobregat

frecerca.ceic@sjd.es

Centros

Activo (14/06/2023)

CENTRE SOCIOSANITARI SANT JORDI DE LA VALL D'HEBRON

Barcelona

BARCELONA

Oncología y Hematología Pediatrica

Activo (19/05/2023)

Complejo Hospitalario La Paz

Madrid

MADRID

Oncología y Hematología Pediatrica

Activo (11/10/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Oncología y Hematología Pediatrica

Activo (25/05/2023)

FUNDACIO HOSPITAL SANT JOAN DE DEU

Martorell

BARCELONA

Oncología

Activo (16/05/2023)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Oncohematología Pediátrica

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

N/A

Activo (16/05/2023)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

Oncología y Hematología Pediatrica

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

N/A

Activo (17/05/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología Pediatrica

Activo (08/03/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

N/A

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

Universidade De Santiago De Compostela

Santiago De Compostela

CORUÑA

N/A

Medicamentos

Dexamethason 0,5 mg JENAPHARM®
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

MITOXANTRONE HYDROCHLORIDE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

BESPONSA 1 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01FB01 - INOTUZUMAB OZOGAMICINA
Principios Activos: N/A

Experimental

Vincristine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS USE

Código ATC: L01CA02 - VINCRISTINA
Principios Activos: N/A

Experimental

DEXAMETHASONE SODIUM PHOSPHATE
SOLUTION FOR INJECTION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

CRISANTASPASE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Oncaspar 750 U/ml powder for solution for injection/infusion.
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

Código ATC: L01XX24 - PEGASPARGASA
Principios Activos: N/A

Experimental

Sin resultados

A Phase 2 Superiority Study with InO Monotherapy vs ALLR3 for Induction Treatment of Childhood HR or VHR First Relapse BCP ALL

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18
Gender	**Phases**	**Expected Participants**
Both	Phase II	9
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, pharmacokinetics, pharmacodynamics, pharmacogenomics	NO

Information

Identifier
2023-509810-13-00 (CTIS)

Protocol Code
B1931036

Transitioned 2022-000186-40

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

Investigated Disease
Acute Lymphoblastic Leukemia (ALL)

Scientific Title
B1931036 - A PROSPECTIVE, RANDOMIZED, OPEN-LABEL PHASE 2 STUDY TO EVALUATE THE SUPERIORITY OF INOTUZUMAB OZOGAMICIN MONOTHERAPY VERSUS ALLR3 FOR INDUCTION TREATMENT OF CHILDHOOD HIGH- RISK OR VERY HIGH-RISK FIRST RELAPSE B-CELL PRECURSOR

ACUTE LYMPHOBLASTIC LEUKAEMIA

Rationale

Not provided

Main Objective

To demonstrate the superiority of InO monotherapy vs ALLR3induction in paediatric participants between 1 and <18 years with HR or VHR first bone marrow relapse CD22-positive BCP ALL

Primary Endpoints

Minimal residual disease (MRD)-negative, CR/CRp/CRi (per investigator assessment) at the end of induction therapy (MRD negativity is assessed by central lab and defined as leukemic blasts <1x10-4 by real time quantitative polymerase chain reaction (RQ-PCR) [with reflex to FC result if MRD is non-evaluable by RQ-PCR]).

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the long-term efficacy of InO monotherapy vs ALLR3 regimen with respect to event-free survival (EFS).
To evaluate the long-term efficacy of InO monotherapy vs ALLR3 regimen with respect to: Duration of response (DOR) Hematopoietic stem cell transplant (HSCT) rate Chimeric antigen receptor (CAR) T-cell therapy rate Overall survival (OS)
To evaluate the safety and tolerability of InO monotherapy vs ALLR3 induction
To evaluate the pharmacokinetics (PK) of InO

Secondary Endpoints

EFS, defined as the time from randomization until objective progression, relapse from CR/CRp/CRi, based on investigator assessment per response criteria, failure to achieve CR/CRp/CRi by the end of induction, MRD persistence prior to HSCT, second malignancy, or death due to any cause.
DOR, defined as time from date of first documented response (CR/CRp/CRi) to the date of first documented objective progression, relapse from CR/CRp/CRi as determined by investigator assessment per modified NCCN response criteria, MRD persistence prior to HSCT, or death due to any cause, whichever occurs first.
HSCT (and CAR T-cell therapy) rate, defined as the number and percentage of participants being transplanted and those receiving CAR Tcell therapy after treatment with InO or ALLR3.
OS, defined as the time from the date of randomization to the date of death due to any cause.
Incidence and severity of AEs graded per NCI CTCAE v4.03.
Cmax and Ctrough

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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use a permitted concomitant medication(s). Refer to Section 6.8,, Concomitant Therapy. Any vaccination with live viral vaccines within 2 weeks of the start of study therapy. Administration of an IP (eg, drug or vaccine) concurrent with study intervention or within 30 days (or as determined by the local requirement) or 5 half-lives preceding the first dose of study intervention used in this study (whichever is longer). A participant may be eligible if they are in the follow-up phase of an investigational study if they meet the criterion for time elapsed from previous administration of IP. Cases must be discussed with sponsor's medical monitor to judge eligibility. Diagnostic Assessments: Serum or urine pregnancy test positive at screening. Baseline 12 lead ECG that demonstrates clinically relevant abnormalities that may affect participant safety or interpretation of study results (eg, QTcF interval >470 msec, complete LBBB, signs of an acute or indeterminate age myocardial infarction, STT interval changes suggestive of myocardial ischemia, second- or thirddegree AV block, or serious bradyarrhythmias or tachyarrhythmias). If QTcF >470 msec, the ECG should be repeated 2 more times the average of the 3 QTcF values should be used to determine the participants eligibility. Computer interpreted ECGs should be overread locally by a physician experienced in reading ECGs before excluding participants. Participants with active infection, including (but not limited to) HBV, HCV, and known HIV or AIDS-related illness. HIV infection with CD4+ count <200/mm3 and viral load of >400 copies/mm3. Participants with stable well-controlled HIV infection may be eligible after consultation with the sponsor. HBV Participants with a positive HBsAg (ie, either acute or chronic active hepatitis) are excluded. Participants with HBV antibody positivity indicating immunity, either due to vaccination or prior natural infection, are eligible. Participants with positive anti-HBcAb but negative HBsAg and anti- HBsAb profile, depending on clinical circumstances, may be eligible. Discussion with the sponsor is indicated. HCV Participants with active HCV as determined by viral load.

Calendar

(Last Update: 17/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/12/2022	16/05/2023	20/06/2023	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

Pfizer Inc. United States

66 Hudson Boulevard East

Contact Person

Clinical Medical Lead

+18007181021

ClinicalTrials.gov_Inquiries@pfizer.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Fundacio Sant Joan de Deu

Santa Rosa, 39-57, 3a planta 08950 Esplugues de Llobregat

frecerca.ceic@sjd.es

Sites

Active (14/06/2023)

CENTRE SOCIOSANITARI SANT JORDI DE LA VALL D'HEBRON

Barcelona

BARCELONA

Oncología y Hematología Pediatrica

Active (19/05/2023)

Complejo Hospitalario La Paz

Madrid

MADRID

Oncología y Hematología Pediatrica

Active (11/10/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Oncología y Hematología Pediatrica

Active (25/05/2023)

FUNDACIO HOSPITAL SANT JOAN DE DEU

Martorell

BARCELONA

Oncología

Active (16/05/2023)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Oncohematología Pediátrica

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

N/A

Active (16/05/2023)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

Oncología y Hematología Pediatrica

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

N/A

Active (17/05/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología Pediatrica

Active (08/03/2024)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

N/A

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

Universidade De Santiago De Compostela

Santiago De Compostela

CORUÑA

N/A

Medication

Dexamethason 0,5 mg JENAPHARM®
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

MITOXANTRONE HYDROCHLORIDE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

BESPONSA 1 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: L01FB01 - INOTUZUMAB OZOGAMICINA
Active Principles: N/A

Experimental

Vincristine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS USE

ATC code: L01CA02 - VINCRISTINA
Active Principles: N/A

Experimental

DEXAMETHASONE SODIUM PHOSPHATE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A

Experimental

CRISANTASPASE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

Dexamethason 4 mg JENAPHARM®
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

Oncaspar 750 U/ml powder for solution for injection/infusion.

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS USE

ATC code: L01XX24 - PEGASPARGASA

Active Principles: N/A

Experimental

No results