

ALL SCTped 2012 FORUM - Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Adultos (18-64 años)

Género

Ambos

Fases

Fase II , Fase III

Participantes esperados

450

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

tratamiento, seguridad, eficacia,
farmacocinética, farmacogenómica

Terapia avanzada

NO

Información

Identificador

2024-512657-24-00 (CTIS)

Cod. Protocolo

ALL SCTped FORUM

Transicionado 2012-003032-22

Área terapéutica

- Enfermedades [C] - Hematología [C15]
- Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Acute Lymphoblastic Leukaemia

Título Científico

ALL SCTped 2012 FORUM - Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia

Justificación

No aportado

Objetivo Principal

Stratum 1 randomised question (closed in December 2018, randomised patients in active follow-up): To show that a non-total body irradiation (TBI) containing conditioning (Flu/Thio/ivBu or Flu/Thio/Treo) results in a non-inferior survival as compared to conditioning with TBI/Etoposide in children older than 4 years after HSCT from a Human leucocyte antigen (HLA) identical sibling donor (MSD) or an HLA matched donor (MD).

Stratum 1 MSD/MD: To explore the impact of risk factors on the incidence of adverse events of special interest (AESIs) and on overall survival and event free survival in the entire cohort (question 3 and 5).

Stratum 1 MSD/MD in age-group 2-4 years: To explore incidence of adverse events of special interest (AESIs) and short-term overall survival and event free survival in the entire cohort receiving TBI/VP16 conditioning regimen.

Stratum 2 MMD: To explore event free survival (EFS) after HSCT from HLA mismatched donors using mismatched unrelated donors (MMD), mismatched cord blood or HLA haplo-identical family members.

Variables de Evaluación Primaria

Stratum 1: Overall Survival (OS)

Stratum 2: Event Free Survival (EFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

Stratum 1: EFS

Stratum 2: OS

Stratum 1 and 2: Cumulative Incidence of Treatment-related mortality (TRM)

Stratum 1 and 2: Cumulative Incidence of Relapse

Stratum 1 and 2: Toxicity: acute and late

Stratum 1 and 2: Acute Graft versus Host Disease (aGVHD) and chronic GVHD (cGVHD)

Stratum 1 and 2: Secondary malignancies

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

All patients with ALL (except for patients with mature B-ALL) who fulfil the following criteria:
Age at diagnosis 18 years OR age at HSCT 21 years
Indication for allogeneic HSCT
Complete remission (CR) before SCT
Written consent of the parents (legal guardian) and, if necessary, the minor patient via Informed Consent Form
No pregnancy
No secondary malignancy
No previous HSCT
HSCT is performed in a study participating centre

Criterios de Exclusión

Patients who do not fulfil the inclusion criteria Non-Hodgkin Lymphoma Whole protocol and/or its essential parts are refused either by the patient himself/herself or the respective legal guardian No consent is given for saving and propagation of anonymous medical data for study reasons Severe concomitant disease that does not allow treatment according to the protocol at the investigators discretion e.g.: malformation syndromes, cardiac malformations, metabolic disorders; renal impairment (< 30% of normal glomerular filtration rate); severe pulmonary, hepatic or cardiac impairment due to toxicity or infection Karnofsky / Lansky score < 50% Subjects unwilling or unable to comply with the study procedures

Calendario

(Última actualización: 29/06/2026)

Autorización 12/02/2018	Inicio de Ensayo 12/02/2018	Inclusión Primer Paciente 10/10/2024	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

St. Anna Childrens Cancer Research Institute GmbH Austria

Zimmermannplatz 10Alsergrund

Contact Person

Christina Peters

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

ceic@vhir.org

934894010

Centros

Activo (12/06/2018)	COMPLEJO HOSPITALARIO REGIONAL DE MÁLAGA Málaga	No iniciado (---/---/----)	Fundacio Hospital Universitari Vall DHebron Institut De Recerca Barcelona BARCELONA Jefe de Sección Servicio de Oncología y Hem. Ped. Vall dHebron Barcelona Hosp. Campus
Activo (12/06/2018)	HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA Murcia MURCIA	No iniciado (---/---/----)	Hospital De La Santa Creu I Sant Pau Barcelona BARCELONA Unidad de Hematología, Oncología y Trasplante Hematopoyético Servicio de Pediatría
Activo (12/06/2018)	Hospital de la Santa Creu i Sant Pau Barcelona BARCELONA	Activo (17/05/2018)	Hospital Universitari Vall d'Hebron Barcelona BARCELONA
Activo (12/06/2018)	HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS Oviedo ASTURIAS		

Medicamentos

**ANTI-HUMAN T-LYMPHOCYTE
IMMUNOGLOBULIN FROM RABBITS**
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental

**BLINCYTO 38.5 micrograms powder for
concentrate and solution for solution for
infusion.**

SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FX07 - BLINATUMOMAB
Principios Activos: N/A

Huérfano

Experimental

THIOTEPA
POWDER FOR CONCENTRATE FOR SOLUTION FOR
INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental

TREOSULFAN
POWDER FOR SOLUTION FOR INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental

**RABBIT ANTI-HUMAN THYMOCYTE
IMMUNOGLOBULIN**
POWDER FOR SOLUTION FOR INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental

FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

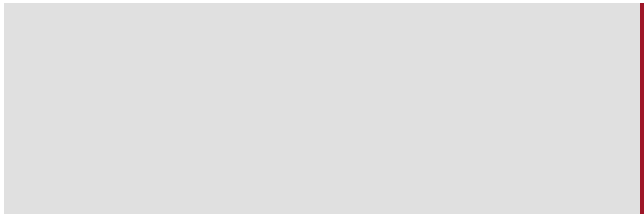
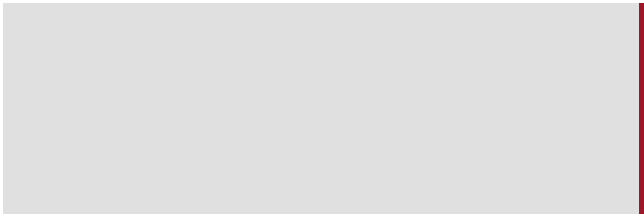
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Principios Activos: N/A

Experimental

BUSULFAN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

—
Principios Activos: N/A

Experimental



ETOPOSIDE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

Principios Activos: N/A

Experimental

Sin resultados

ALL SCTped 2012 FORUM - Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia

State Recruiting	Type of participants Not provided	Age Ranges Adults (18-64 years)
Gender Both	Phases Phase II , Phase III	Expected Participants 450
Results No results	Low level of intervention No	Rare disease No
Geographic coverage Undetermined	Areas of the study treatment, safety, effectiveness, pharmacokinetics, pharmacogenomics	Advanced therapy NO

Information

Identifier 2024-512657-24-00 (CTIS)	Protocol Code ALL SCTped FORUM
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Transitioned 2012-003032-22

Therapeutic area
·Diseases [C] - Hemic and Lymphatic Diseases [C15]
·Diseases [C] - Cancer [C04]

Investigated Disease
Acute Lymphoblastic Leukaemia

Scientific Title
ALL SCTped 2012 FORUM - Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia

Rationale

Not provided

Main Objective

Stratum 1 randomised question (closed in December 2018, randomised patients in active follow-up): To show that a non-total body irradiation (TBI) containing conditioning (Flu/Thio/ivBu or Flu/Thio/Treo) results in a non-inferior survival as compared to conditioning with TBI/Etoposide in children older than 4 years after HSCT from a Human leucocyte antigen (HLA) identical sibling donor (MSD) or an HLA matched donor (MD).

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Stratum 2 MMD: To explore event free survival (EFS) after HSCT from HLA mismatched donors using mismatched unrelated donors (MMD), mismatched cord blood or HLA haplo-identical family members.

Primary Endpoints

Stratum 1: Overall Survival (OS)

Stratum 2: Event Free Survival (EFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Stratum 1: EFS

Stratum 2: OS

Stratum 1 and 2: Cumulative Incidence of Treatment-related mortality (TRM)

Stratum 1 and 2: Cumulative Incidence of Relapse

Stratum 1 and 2: Toxicity: acute and late

Stratum 1 and 2: Acute Graft versus Host Disease (aGVHD) and chronic GVHD (cGVHD)

Stratum 1 and 2: Secondary malignancies

Temporary moments of secondary assessment

Not provided

Inclusion criteria

All patients with ALL (except for patients with mature B-ALL) who fulfil the following criteria:
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 No pregnancy
 No secondary malignancy
 No previous HSCT
 HSCT is performed in a study participating centre

Exclusion criteria

Patients who do not fulfil the inclusion criteria Non-Hodgkin Lymphoma Whole protocol and/or its essential parts are refused either by the patient himself/herself or the respective legal guardian No consent is given for saving and propagation of anonymous medical data for study reasons Severe concomitant disease that does not allow treatment according to the protocol at the investigators discretion e.g.: malformation syndromes, cardiac malformations, metabolic disorders; renal impairment (< 30% of normal glomerular filtration rate); severe pulmonary, hepatic or cardiac impairment due to toxicity or infection Karnofsky / Lansky score < 50% Subjects unwilling or unable to comply with the study procedures

Calendar

(Last Update: 29/06/2026)

Authorization 12/02/2018	Start of Trial 12/02/2018	First patient inclusion 10/10/2024	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

St. Anna Childrens Cancer Research Institute GmbH Austria

Zimmermannplatz 10Alsergrund

Contact Person

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christina.peters@stanna.at

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

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Sites

Active (12/06/2018)	COMPLEJO HOSPITALARIO REGIONAL DE MÁLAGA Málaga	not initialized (---/---/----)	Fundacio Hospital Universitari Vall DHebron Institut De Recerca Barcelona BARCELONA Jefe de Sección Servicio de Oncología y Hem. Ped. Vall dHebron Barcelona Hosp. Campus
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Active (12/06/2018)	Hospital de la Santa Creu i Sant Pau Barcelona BARCELONA	Active (17/05/2018)	Hospital Universitari Vall d'Hebron Barcelona BARCELONA
Active (12/06/2018)	HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS Oviedo ASTURIAS		

Medication

**ANTI-HUMAN T-LYMPHOCYTE
IMMUNOGLOBULIN FROM RABBITS**
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

**BLINCYTO 38.5 micrograms powder for
concentrate and solution for solution for
infusion.**

SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FX07 - BLINATUMOMAB

Active Principles: N/A

Orphan

Experimental

THIOTEPA
POWDER FOR CONCENTRATE FOR SOLUTION FOR
INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

TREOSULFAN
POWDER FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

**RABBIT ANTI-HUMAN THYMOCYTE
IMMUNOGLOBULIN**
POWDER FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

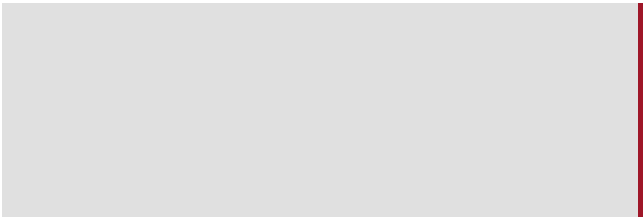
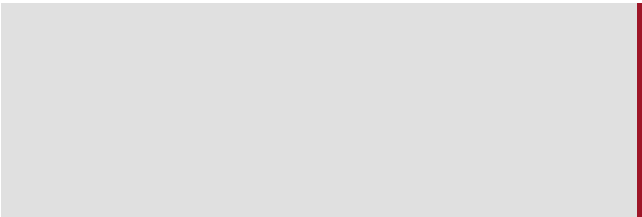
Experimental

BUSULFAN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental



ETOPOSIDE

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS

Active Principles: N/A

Experimental

No results