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

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II , Fase III	450
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacogenómica	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	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/02/2018	12/02/2018	10/10/2024	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

St. Anna Childrens Cancer Research Institute GmbH Austria

Zimmermannplatz 10Alsergrund

Contact Person

Christina Peters

+1401703100

christina.peters@stanna.at

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

-

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

Information

Identifier

2024-512657-24-00 (CTIS)

Protocol Code

ALL SCTped FORUM

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).
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.

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:
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

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

St. Anna Childrens Cancer Research Institute GmbH Austria

Zimmermannplatz 10Alsergrund

Contact Person

Christina Peters

+1401703100

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

ceic@vhir.org

934894010

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

Active (12/06/2018)

HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Unidad de Hematología, Oncología y Trasplante Hematopoyético Servicio de Pediatría

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