# 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).
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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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HSCT is performed in a study participating centre

## Exclusion criteria

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# 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 (--/--/----)

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Active (12/06/2018)

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Murcia

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

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**HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS**

Oviedo

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# Medication

### ANTI-HUMAN T-LYMPHOCYTE IMMUNOGLOBULIN FROM RABBITS

CONCENTRATE FOR SOLUTION FOR INFUSION

INTRAVENOUS

-

Active Principles: N/A

Experimental

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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