International trial in Philadelphia chromosome-positive acute lymphoblastic leukemia

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años) , Lactantes y preescolar (28 días - 23 meses) , Recién nacidos (0-27 días)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	306
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-515499-12-00 (CTIS)

Cod. Protocolo
EsPhALL2017/COGAALL1

Transicionado 2017-000705-20

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

Enfermedad investigada
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia

Título Científico

International phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones

Justificación

No aportado

Objetivo Principal

To compare disease-free survival (DFS) of Standard Risk (SR) pediatric Ph+ ALL treated with continuous imatinib combined with either a highrisk COG ALL chemotherapy backbone or the more intensive EsPhALL chemotherapy backbone.

Variables de Evaluación Primaria

The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events
The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events
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The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Patients should be enrolled on National ALL protocol prior to enrollment on EsPhALL2017/COGAALL1631. Regardless of initial frontline protocol baseline diagnostic samples must be available to develop an MRD probe. Diagnostic samples will be collected and analyzed according to the procedures of the National front-line protocol. 2. > 1 year and < 21 years at ALL diagnosis 3. New LLA diagnosis a. type B or T, or mixed phenotypic acute leukemia (MPAL meeting 2016 WHO definition) with definitive evidence of BCR-ABL1 fusion by karyotype, FISH and/or RT-PCR b. type B, with definitive evidence of ABL class fusions identified according to National/Center procedures of each participating country. 4. Prior Therapy for BCR-ABL1 fusion patients: a. induction therapy, which includes vincristine, a corticosteroid, usually PEG-L-Asparaginase, with or without anthracycline, and/or other standard cytotoxic chemotherapy. b. Not received more than 14 days of multiagent induction therapy beginning with the first dose of vincristine. c. May have started imatinib prior to study entry but have not received more than 14 days of imatinib. 5. Prior Therapy for ABL-class fusion patients: a. must have previously completed the 4 or 5 weeks of multiagent Induction chemotherapy. b. may have started imatinib during Induction IA, at the same time of or after the first vincristine dose. 6. Patients must have a performance status corresponding to ECOG scores of 0, 1, or 2. 7. Adequate liver function. 8. Adequate cardiac function. 9. Adequate renal function.

Criterios de Exclusión

1. Known history of chronic myelogenous leukemia (CML).
2. ALL developing after a previous cancer treated with cytotoxic chemotherapy.
3. Active, uncontrolled infection or active systemic illness that requires ongoing vasopressor support or mechanical ventilation
4. Down syndrome
5. Pregnancy
6. Breast Feeding
7. Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of treatment according to protocol.
8. Patients with congenital long QT syndrome, history of ventricular arrhythmias or heart block.
9. Prior treatment with dasatinib, or any TKI inhibitor other than imatinib.

Calendario

(Última actualización: 25/10/2024)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/01/2021	30/07/2021	30/07/2021	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

Universita Degli Studi Di Milano Bicocca Italy

Piazza Dell'ateneo Nuovo 1

Contact Person

Scientific coordinator

00390392332314

esphall@unimib.it

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm de Cantabria

Edificio IFIMAV 3ª Planta Avda Cardenal Herrera Oria s/n 39011 Santander

eclinicos4@idival.org

942315514

Centros

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

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

pediatric oncology

No iniciado (27/01/2021)

HOSPITAL CLINICO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Pediatrics

Activo (30/07/2021)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

No iniciado (27/01/2021)

HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE

Alicante/Alacant

ALICANTE

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

pediatric oncology

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

pediatric oncology

No iniciado (27/01/2021)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

Pediatric Hematology & Oncology

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

Hospital Sant Joan De Deu Barcelona

Esplugues De Llobregat

BARCELONA

pediatric oncology

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

Hospital Universitari Vall D Hebron

Barcelona

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pediatric oncology

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

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

pediatric oncology

No iniciado (27/01/2021)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Pediatrics

Activo (29/06/2021)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

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

Hospital Universitario Miguel Servet

Zaragoza

ZARAGOZA

pediatric oncology

No iniciado (27/01/2021)

Hospital Universitario Regional De Malaga

Málaga

MÁLAGA

No iniciado (27/01/2021)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

Valencia

VALENCIA

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

pediatric oncology

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

University Hospital Son Espases

Palma

BALEARES

pediatric oncology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

pediatric oncology

Medicamentos

DELTACORTENE 25 mg compresse

TABLET

ORAL AND IV

Código ATC: H02AB07 - PREDNISONA

Principios Activos: N/A

Experimental

IMATINIB

FILM-COATED TABLET

ORAL USE

-

Principios Activos: N/A

Experimental

DAUNORUBICIN HYDROCHLORIDE

SOLUTION FOR INJECTION

INJECTION

-

Principios Activos: N/A

Experimental

ETOPOSIDE

SOLUTION FOR INFUSION

INFUSION

-

Principios Activos: N/A

Experimental

MERCAPTOPURINE

TABLETS

ORAL USE

-

Principios Activos: N/A

Experimental

CYTARABINE

SUSPENSION FOR INJECTION

INJECTION

-

Principios Activos: N/A

Experimental

METHOTREXATE

SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

INTRAVENOUS, INTRA-ARTERIAL, INTRATHECAL USE

-

Principios Activos: N/A

Experimental

DEXAMETHASONE

TABLET

ORAL AND IV

-

Principios Activos: N/A

Experimental

METHOTREXATE
TABLET
ORAL

-
Principios Activos: N/A

Experimental

TIOGUANINE
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE
INJECTION/INFUSION
INJECTION

-
Principios Activos: N/A

Experimental

Decortin H 5 mg töflur
TABLET
ORAL USE

Código ATC: H02AB06 - PREDNISOLONA
Principios Activos: N/A

Experimental

IFOSFAMIDE
SOLUTION FOR INFUSION
INFUSION

-
Principios Activos: N/A

Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INJECTION

-
Principios Activos: N/A

Experimental

Erwinase 10 000 U polvere per soluzione iniettabile/per infusione.
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Vincristina Teva Italia 1 mg/ml soluzione iniettabile
INJECTION
INJECTION

Código ATC: L01XX02 - ASPARAGINASA
Principios Activos: N/A
Experimental

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

PEGASPARGASE
SOLUTION FOR INJECTION
INFUSION

-
Principios Activos: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION OR INFUSION
INTRATHECAL USE

-
Principios Activos: N/A
Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INFUSION

-
Principios Activos: N/A
Experimental

HYDROCORTISONE SODIUM SUCCINATE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Principios Activos: N/A
Experimental

Sin resultados

International trial in Philadelphia chromosome-positive acute lymphoblastic leukemia

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years) , Infants and preschool (28 days - 23 months) , Newborn infants (0-27 days)
Gender	**Phases**	**Expected Participants**
Both	Phase III	306
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	treatment, safety, effectiveness	NO

Information

Identifier
2024-515499-12-00 (CTIS)

Protocol Code
EsPhALL2017/COGAALL1

Transitioned 2017-000705-20

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

Investigated Disease
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia
Acute lymphoblastic leukemia

Scientific Title

International phase 3 trial in Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) testing imatinib in combination with two different cytotoxic chemotherapy backbones

Rationale

Not provided

Main Objective

To compare disease-free survival (DFS) of Standard Risk (SR) pediatric Ph+ ALL treated with continuous imatinib combined with either a highrisk COG ALL chemotherapy backbone or the more intensive EsPhALL chemotherapy backbone.

Primary Endpoints

The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events
The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events
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The primary endpoint, DFS, is defined as the time from randomization to first event (relapse, second malignancy, or death in complete remission) or time to last followup for patients without events

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Patients should be enrolled on National ALL protocol prior to enrollment on EsPhALL2017/COGAALL1631. Regardless of initial frontline protocol baseline diagnostic samples must be available to develop an MRD probe. Diagnostic samples will be collected and analyzed according to the procedures of the National front-line protocol. 2. > 1 year and < 21 years at ALL diagnosis 3. New LLA diagnosis a. type B or T, or mixed phenotypic acute leukemia (MPAL meeting 2016 WHO definition) with definitive evidence of BCR-ABL1 fusion by karyotype, FISH and/or RT-PCR b. type B, with definitive evidence of ABL class fusions identified according to National/Center procedures of each participating country. 4. Prior Therapy for BCR-ABL1 fusion patients: a. induction therapy, which includes vincristine, a corticosteroid, usually PEG-L-Asparaginase, with or without anthracycline, and/or other standard cytotoxic chemotherapy. b. Not received more than 14 days of multiagent induction therapy beginning with the first dose of vincristine. c. May have started imatinib prior to study entry but have not received more than 14 days of imatinib. 5. Prior Therapy for ABL-class fusion patients: a. must have previously completed the 4 or 5 weeks of multiagent Induction chemotherapy. b. may have started imatinib during Induction IA, at the same time of or after the first vincristine dose. 6. Patients must have a performance status corresponding to ECOG scores of 0, 1, or 2. 7. Adequate liver function. 8. Adequate cardiac function. 9. Adequate renal function.

Exclusion criteria

1. Known history of chronic myelogenous leukemia (CML).
2. ALL developing after a previous cancer treated with cytotoxic chemotherapy.
3. Active, uncontrolled infection or active systemic illness that requires ongoing vasopressor support or mechanical ventilation
4. Down syndrome
5. Pregnancy
6. Breast Feeding
7. Sexually active patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of treatment according to protocol.
8. Patients with congenital long QT syndrome, history of ventricular arrhythmias or heart block.
9. Prior treatment with dasatinib, or any TKI inhibitor other than imatinib.

Calendar

(Last Update: 25/10/2024)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/01/2021	30/07/2021	30/07/2021	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

Universita Degli Studi Di Milano Bicocca Italy

Piazza Dell'ateneo Nuovo 1

Contact Person

Scientific coordinator

00390392332314

esphall@unimib.it

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm de Cantabria

Edificio IFIMAV 3ª Planta Avda Cardenal Herrera Oria s/n 39011 Santander

eclinicos4@idival.org

942315514

Sites

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

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

pediatric oncology

not initialized (27/01/2021)

HOSPITAL CLINICO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Pediatrics

Active (30/07/2021)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

not initialized (27/01/2021)

HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE

Alicante/Alacant

ALICANTE

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

Hospital General Universitario Gregorio Maranon

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HOSPITAL UNIVERSITARIO LA PAZ

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Pediatrics

Active (29/06/2021)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

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CANTABRIA

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Hospital Universitario Regional De Malaga

Málaga

MÁLAGA

not initialized (27/01/2021)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

Valencia

VALENCIA

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

pediatric oncology

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

University Hospital Son Espases

Palma

BALEARES

pediatric oncology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

pediatric oncology

Medication

DELTACORTENE 25 mg compresse

TABLET

ORAL AND IV

ATC code: H02AB07 - PREDNISONA

Active Principles: N/A

Experimental

IMATINIB

FILM-COATED TABLET

ORAL USE

-

Active Principles: N/A

Experimental

DAUNORUBICIN HYDROCHLORIDE

SOLUTION FOR INJECTION

INJECTION

-

Active Principles: N/A

Experimental

ETOPOSIDE

SOLUTION FOR INFUSION

INFUSION

-

Active Principles: N/A

Experimental

MERCAPTOPURINE

TABLETS

ORAL USE

-

Active Principles: N/A

Experimental

CYTARABINE

SUSPENSION FOR INJECTION

INJECTION

-

Active Principles: N/A

Experimental

METHOTREXATE

SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

INTRAVENOUS, INTRA-ARTERIAL, INTRATHECAL USE

-

Active Principles: N/A

Experimental

DEXAMETHASONE

TABLET

ORAL AND IV

-

Active Principles: N/A

Experimental

METHOTREXATE
TABLET
ORAL

-
Active Principles: N/A

Experimental

TIOGUANINE
TABLET
ORAL USE

-
Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE
INJECTION/INFUSION
INJECTION

-
Active Principles: N/A

Experimental

Decortin H 5 mg töflur
TABLET
ORAL USE

ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A

Experimental

IFOSFAMIDE
SOLUTION FOR INFUSION
INFUSION

-
Active Principles: N/A

Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INJECTION

-
Active Principles: N/A

Experimental

Erwinase 10 000 U polvere per soluzione iniettabile/per infusione.
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Vincristina Teva Italia 1 mg/ml soluzione iniettabile
INJECTION
INJECTION

ATC code: L01XX02 - ASPARAGINASA
Active Principles: N/A
Experimental

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

PEGASPARGASE
SOLUTION FOR INJECTION
INFUSION

-
Active Principles: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION OR INFUSION
INTRATHECAL USE

-
Active Principles: N/A
Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INFUSION

-
Active Principles: N/A
Experimental

HYDROCORTISONE SODIUM SUCCINATE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Active Principles: N/A
Experimental

No results