NOPHO-DBH AML 2012 Protocol: Research study for treatment of children and adolescents with acute myeloid leukemia 0-18 years

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	930
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	tratamiento, eficacia	NO

Información

Identificador

2024-518254-16-00 (CTIS)

Cod. Protocolo

No aportado

Transicionado 2012-002934-35

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Acute Myeloid Leukemia (Pediatric 0-18 years)

Título Científico

NOPHO-DBH AML 2012 Protocol: Research study for treatment of children and adolescents with acute myeloid leukemia 0-18 years

Justificación

No aportado

Objetivo Principal

The AML 2012 study is a treatment and research protocol with the overall aim of improving prognosis for children and adolescents with AML. This is to be achieved by better risk stratification based on MRD quantification and more intensive induction compared to previous NOPHO protocols.
Specific research aims are 1) To investigate if DaunoXome® has a higher efficacy than Mitoxantrone, when given in course 1 for treatment of pediatric AML
2) To investigate if FLADx has a higher efficacy than ADxE when given as the second induction course for treatment of pediatric AML
3) To investigate the correlation between MRD measurement by PCR and flow cytometry and the prognostic impact of MRD with either method after course 1 and 2 respectively.

Variables de Evaluación Primaria

The fraction of patients who achieve an MRD level below 0.1%, as quantified by flow cytometry, after the first induction course. (aim 1)
The fraction of patients who achieve an MRD level below 0.1%, as quantified by flow cytometry, after the second induction course (aim 2)
For patients with fusion genes MRD levels after course 1 and 2 (aim 3)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Improving both EFS and OS as compared to NOPHO-AML 93 and 2004.
Improving EFS and OS for patients with intermediate response (5- 14.9%) blasts after course 1 and patients with t(8;21).
Achieving improved anti-leukaemic effect with no increase or a decrease in early toxic deaths and deaths in CR.
Comparing outcome in subgroups of patients as defined by characteristics of both patients and disease such as age, FAB type and cytogenetics (e.g. t(8;21, inv(16) and MLL rearrangements).as defined by both patient and disease characteristics such as age and cytogenetics
Compare the incidence of severe infections and severe organ toxicity in the treatment arms and with previous protocols

Variables de Evaluación Secundaria

Event-free survival and overall survival at five years
The median MRD after course 1 and course 2.

The rate of CR after one and two induction courses.
Cardiac function after one and five years.
Frequency of severe adverse events as defined in section 14.2.3 in the protocol, early deaths and deaths in CR

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

AML as defined by the diagnostic criteria in the protocol
Age below 19 years at time of diagnosis
Written informed consent

Criterios de Exclusión

Previous chemotherapy or radiotherapy. This includes patient with secondary AML after previous cancer therapy. They can be treated according to the protocol but will not be included in the study population. Secondary AML has a poorer response to chemotherapy but may benefit from SCT if the procedure can be tolerated.
Positive pregnancy test
Lactating female or female of childbearing potential not using adequate contraception
AML secondary to previous bone marrow failure syndrome.
Down syndrome (DS). Patients with myeloid leukaemia of Down syndrome are recommended to be treated according to the international ML-DS protocol. Patients with AML and DS older than 5 years who often lack GATA1 mutation and do not have typical myeloid leukaemia of DS may be treated according to the protocol but will not be included in the study population.
Acute promyelocytic leukaemia (APL). These patients are recommended treatment according to the international APL Study.
Myelodysplastic syndrome (MDS). These patients are recommended treatment according to EWOG-MDS.
Juvenile Myelomonocytic Leukaemia (JMML). These patients are recommended treatment according to EWOG-MDS.
Known intolerance to any of the chemotherapeutic drugs in the protocol.
Fanconi anemia
Major organ failure precluding administration of planned therapy

Calendario

(Última actualización: 22/11/2024)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
14/03/2017	14/07/2017	01/09/2017	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
10/09/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Vaestra Goetalandsregionen Sweden

Regionens Hus

Contact Person

Jonas Abrahamsson

0046313421000

jonas.abrahamsson@vgregion.se

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

CEIm del Hospital Universitario y Politécnico la Fe

Avda de Fernando Abril Martorell, n.106, Hospital U. i P. La Fe, Torre A, Planta 7, despacho 7.12, 46026 Valencia

ceic@iislafe.es

961246605

Centros

No iniciado (02/03/2018)

COMPLEJO HOSPITALARIO REGIONAL DE MÁLAGA

Málaga

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

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Pediatric oncology department

No iniciado (13/04/2018)

COMPLEJO HOSPITALARIO UNIVERSITARIO INSULAR-MATERNO INFANTIL

Palmas de Gran Canaria, Las

LAS PALMAS

No iniciado (14/03/2017)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

No iniciado (02/03/2018)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

No iniciado (20/03/2018)

HOSPITAL CLÍNICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

No iniciado (14/03/2017)

Hospital de la Santa Creu i Sant Pau

Barcelona

BARCELONA

No iniciado (02/03/2018)

Hospital de Sant Joan de Déu

Esplugues de Llobregat

BARCELONA

No iniciado (14/03/2017)

HOSPITAL GENERAL UNIVERSITARIO DE ALICANTE

Alicante/Alacant

ALICANTE

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Pediatric oncology department

No iniciado (14/03/2017)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Pediatric oncology department

No iniciado (02/03/2018)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

No iniciado (14/03/2017)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

VALENCIA

No iniciado (20/03/2018)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

No iniciado (02/03/2018)

Hospital Universitari Vall d'Hebron

Barcelona

BARCELONA

No iniciado (02/03/2018)

HOSPITAL UNIVERSITARIO DE CRUCES

Barakaldo

VIZCAYA/BIZKAIA

No iniciado (14/03/2017)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

No iniciado (02/03/2018)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

No iniciado (14/03/2017)

HOSPITAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Medicamentos

MITOXANTRONE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

DAUNORUBICIN
EMULSION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

CYTARABINE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

DAUNORUBICIN HYDROCHLORIDE
POWDER FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

ETOPOSIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-

Principios Activos: N/A

Experimental

Sin resultados

NOPHO-DBH AML 2012 Protocol: Research study for treatment of children and adolescents with acute myeloid leukemia 0-18 years

State	Type of participants	Age Ranges
End of recruitment	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	930
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	treatment, effectiveness	NO

Information

Identifier
2024-518254-16-00 (CTIS)

Protocol Code
No aportado

Transitioned 2012-002934-35

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

Investigated Disease
Acute Myeloid Leukemia (Pediatric 0-18 years)

Scientific Title
NOPHO-DBH AML 2012 Protocol: Research study for treatment of children and adolescents with acute myeloid leukemia 0-18 years

Rationale

Not provided

Main Objective

The AML 2012 study is a treatment and research protocol with the overall aim of improving prognosis for children and adolescents with AML. This is to be achieved by better risk stratification based on MRD quantification and more intensive induction compared to previous NOPHO protocols.
Specific research aims are 1) To investigate if DaunoXome® has a higher efficacy than Mitoxantrone, when given in course 1 for treatment of pediatric AML
2) To investigate if FLADx has a higher efficacy than ADxE when given as the second induction course for treatment of pediatric AML
3) To investigate the correlation between MRD measurement by PCR and flow cytometry and the prognostic impact of MRD with either method after course 1 and 2 respectively.

Primary Endpoints

The fraction of patients who achieve an MRD level below 0.1%, as quantified by flow cytometry, after the first induction course. (aim 1)
The fraction of patients who achieve an MRD level below 0.1%, as quantified by flow cytometry, after the second induction course (aim 2)
For patients with fusion genes MRD levels after course 1 and 2 (aim 3)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Improving both EFS and OS as compared to NOPHO-AML 93 and 2004.
Improving EFS and OS for patients with intermediate response (5- 14.9%) blasts after course 1 and patients with t(8;21).
Achieving improved anti-leukaemic effect with no increase or a decrease in early toxic deaths and deaths in CR.
Comparing outcome in subgroups of patients as defined by characteristics of both patients and disease such as age, FAB type and cytogenetics (e.g. t(8;21, inv(16) and MLL rearrangements).as defined by both patient and disease characteristics such as age and cytogenetics
Compare the incidence of severe infections and severe organ toxicity in the treatment arms and with previous protocols

Secondary Endpoints

Event-free survival and overall survival at five years
The median MRD after course 1 and course 2.

The rate of CR after one and two induction courses.
Cardiac function after one and five years.
Frequency of severe adverse events as defined in section 14.2.3 in the protocol, early deaths and deaths in CR

Temporary moments of secondary assessment

Not provided

Inclusion criteria

AML as defined by the diagnostic criteria in the protocol
Age below 19 years at time of diagnosis
Written informed consent

Exclusion criteria

Previous chemotherapy or radiotherapy. This includes patient with secondary AML after previous cancer therapy. They can be treated according to the protocol but will not be included in the study population. Secondary AML has a poorer response to chemotherapy but may benefit from SCT if the procedure can be tolerated.
Positive pregnancy test
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Known intolerance to any of the chemotherapeutic drugs in the protocol.
Fanconi anemia
Major organ failure precluding administration of planned therapy

Calendar

(Last Update: 22/11/2024)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
14/03/2017	14/07/2017	01/09/2017	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
10/09/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Vaestra Goetalandsregionen Sweden

Regionens Hus

Contact Person

Jonas Abrahamsson

0046313421000

jonas.abrahamsson@vgregion.se

Monetary support: N/A

Sponsor type: No commercial

Ceim

CEIm del Hospital Universitario y Politécnico la Fe

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Sites

not initialized (02/03/2018)

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Málaga

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not initialized (13/04/2018)

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Zaragoza

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not initialized (14/03/2017)

HOSPITAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Medication

MITOXANTRONE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A
Experimental

DAUNORUBICIN
EMULSION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A
Experimental

CYTARABINE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A
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POWDER FOR INFUSION
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Active Principles: N/A
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FLUDARABINE PHOSPHATE
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Active Principles: N/A
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ETOPOSIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A
Experimental

No results