VyClo ITCC-092

Estado	**Tipo de Participantes**	**Rangos de Edad**
Interrumpido	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I	4
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-508050-26-00 (CTIS)

Cod. Protocolo
SP_MH20VYX

Transicionado 2020-000142-34

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

Enfermedad investigada
AML

Título Científico
A Phase Ib study of Vyxeos® (liposomal daunorubicin and cytarabine) in combination with Clofarabine in children with relapsed/refractory AML

Justificación

No aportado

Objetivo Principal

To establish the recommended phase 2 dose of Vyxeos®/CPX-351 in combination with clofarabine in children with relapsed/refractory AML.

Variables de Evaluación Primaria

Frequency of Dose-limiting toxicities (DLTs) during the first course of therapy

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To determine the safety and tolerability of this combination To determine the (preliminary) efficacy in terms of the hematological remission rate in these patients as determined by morphology with flow cytometric confirmation. To describe the durability of response, including the number of patients that undergo stem- cell transplant after re-induction with this regimen

Variables de Evaluación Secundaria

1. Safety and tolerability: frequency of AEs, frequency of clinically significant laboratory abnormalities and number of toxic deaths 2. Measures of anti-leukemic activity3. Overall patient survival and relapse-free survival 4. Number of patients undergoing HSCT after treatment. 5. Serum and intracellular pharmacokinetic parameters 6. Relationship between response (ORR) and Ara-CTP accumulation 7.Correlation between duration of response and measurable residual disease assessed by flow-cytometry

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Any 2nd relapse of AML Refractory AML (defined as 20% blasts in the bone marrow after standard (re-) induction therapy) Early 1st relapse (defined as relapse within one year from initial diagnosis) of AML Any relapse of AML after

prior allogenic HSCT Any relapse of AML with high risk cytogenetic characteristics Complete initial work-up within 7 days prior to study entry, including bone-marrow aspiration, lumbar puncture (without intrathecal therapy) Lansky play score 60 for patients <16 years of age; or Karnofsky performance status 60 for patients 16 years of age Life expectancy > 6 weeks a calculated GFR 70mL/min/1.73 m2 Liver function: total serum bilirubin 3 mg/dl or 50 µmol/L and aspartate transaminase (AST) and alanine transaminase (ALT) 200 U/L Adequate cardiac function (defined as shortening fraction 28% or ejection fraction 50%)

Criterios de Exclusión

evidence of a currently uncontrolled bacterial, viral or parasitic infection evidence of a fungal infection, defined as either: - Pulmonary infiltrates suggestive of a fungal infection at HR-CT (within 3 weeks prior to enrollment) - Positive Aspergillus serum test (galactomannan), according to local laboratory practice (within 3 weeks prior to enrollment) evidence of isolated extramedullary relapse, including isolated CNS-relapse evidence of CNS3 or symptomatic CNS leukemia Down Syndrome evidence of relapsed/refractory acute promyelocytic leukemia (APL) use of any anticancer therapy within 2 weeks before study entry. The patient must have recovered from all acute toxicities from any previous therapy (note: hematological toxicities do not need to be considered since the patient has overt leukemia) history of prior veno-occlusive disease (VOD) known hypersensitivity to cytarabine, clofarabine or liposomal daunorubicin known copper metabolism deficiency, such as Wilson's disease.

Calendario

(Última actualización: 04/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
29/09/2022	24/10/2022	28/10/2022	30/07/2024	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
30/07/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Prinses Maxima Centrum voor Kinderoncologie B.V. Netherlands

Heidelberglaan 25

Contact Person

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31889725206

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Monetary support: N/A

Tipo de promotor: No comercial

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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934894010

Centros

Activo (28/10/2022)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Haematology

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Pedriatrics

Activo (26/10/2022)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

Paediatric Haematology and Oncology

Activo (24/10/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Paediatric Haematology and Oncology

Medicamentos

Evoltra 1 mg/ml concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS

Código ATC: L01BB06 - CLOFARABINA

Principios Activos: N/A

Experimental

Vyxeos Liposomal 44 mg/100 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENOUS

Código ATC: L01XY01 - CITARABINA Y DAUNORUBICINA

Principios Activos: N/A

Experimental

Sin resultados

VyClo ITCC-092

State	Type of participants	Age Ranges
Halted	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I	4
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-508050-26-00 (CTIS)

Protocol Code
SP_MH20VYX

Transitioned 2020-000142-34

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

Investigated Disease
AML

Scientific Title
A Phase Ib study of Vyxeos® (liposomal daunorubicin and cytarabine) in combination with Clofarabine in children with relapsed/refractory AML

Rationale

Not provided

Main Objective

To establish the recommended phase 2 dose of Vyxeos®/CPX-351 in combination with clofarabine in children with relapsed/refractory AML.

Primary Endpoints

Frequency of Dose-limiting toxicities (DLTs) during the first course of therapy

Temporary moments of secondary assessment

Not provided

Secondary Objective

To determine the safety and tolerability of this combination To determine the (preliminary) efficacy in terms of the hematological remission rate in these patients as determined by morphology with flow cytometric confirmation. To describe the durability of response, including the number of patients that undergo stem- cell transplant after re-induction with this regimen

Secondary Endpoints

1. Safety and tolerability: frequency of AEs, frequency of clinically significant laboratory abnormalities and number of toxic deaths 2. Measures of anti-leukemic activity3. Overall patient survival and relapse-free survival 4. Number of patients undergoing HSCT after treatment. 5. Serum and intracellular pharmacokinetic parameters 6. Relationship between response (ORR) and Ara-CTP accumulation 7.Correlation between duration of response and measurable residual disease assessed by flow-cytometry

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 04/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
29/09/2022	24/10/2022	28/10/2022	30/07/2024	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
30/07/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Prinses Maxima Centrum voor Kinderoncologie B.V. Netherlands

Heidelberglaan 25

Contact Person

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31889725206

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Monetary support: N/A

Sponsor type: No commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

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Sites

Active (28/10/2022)

HOSPITAL DE SANT JOAN DE DEU.

Esplugues de Llobregat

BARCELONA

Haematology

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

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Madrid

MADRID

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Active (26/10/2022)

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Madrid

MADRID

Paediatric Haematology and Oncology

Active (24/10/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Paediatric Haematology and Oncology

Medication

Evoltra 1 mg/ml concentrate for solution for infusion

SOLUTION FOR INFUSION

INTRAVENOUS

ATC code: L01BB06 - CLOFARABINA

Active Principles: N/A

Experimental

Vyxeos Liposomal 44 mg/100 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION

INTRAVENOUS

ATC code: L01XY01 - CITARABINA Y DAUNORUBICINA

Active Principles: N/A

Experimental

No results