

VyClo ITCC-092

Estado
Interrumpido

Tipo de Participantes
Sujetos incapaces de otorgar consentimiento

Rangos de Edad
Menores de 18 , Adultos (18-64 años)

Género
Ambos

Fases
Fase I

Participantes esperados
4

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
Si

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
tratamiento, seguridad, eficacia,
farmacocinética

Terapia avanzada
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 activity 3. 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 29/09/2022	Inicio de Ensayo 24/10/2022	Inclusión Primer Paciente 28/10/2022	Interrumpido 30/07/2024	Reiniciado No aportado
Fin de reclutamiento 30/07/2024	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

Prinses Maxima Centrum voor Kinderoncologie B.V. Netherlands

Heidelberglaan 25

Contact Person

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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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Centros

Activo (28/10/2022)	HOSPITAL DE SANT JOAN DE DEU. Esplugues de Llobregat BARCELONA Haematology
	No iniciado (---/---/----)
Activo (26/10/2022)	Hospital Infantil Universitario Nino Jesus Madrid MADRID Pediatrics
	Activo (24/10/2022)
Activo (26/10/2022)	HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS Madrid MADRID Paediatric Haematology and Oncology
	Activo (24/10/2022)
Activo (24/10/2022)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA Paediatric Haematology and Oncology
	Activo (24/10/2022)

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

Halted

Type of participants

Incapable subjects of giving consent

Age Ranges

Less than 18 , Adults (18-64 years)

Gender

Both

Phases

Phase I

Expected Participants

4

Results

No results

Low level of intervention

No

Rare disease

Yes

Geographic coverage

Undetermined

Areas of the study

treatment, safety, effectiveness,
pharmacokinetics

Advanced therapy

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 activity 3. 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

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Contact Person

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Monetary support: N/A

Sponsor type: No commercial

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Sites

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not initialized (---/---/----)	Hospital Infantil Universitario Nino Jesus Madrid MADRID Pediatrics
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Active (24/10/2022)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA Paediatric Haematology and Oncology

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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