Teicoplanin as Infection Prophylaxis in Pediatric Acute Myeloid Leukemia (Pro-Teico study)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	40
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	profilaxis, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-506546-23-00 (CTIS)

Cod. Protocolo
SP_MH19PRO

Transicionado 2020-000508-13

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

Enfermedad investigada
Acute myeloid leukemia

Título Científico
Teicoplanin as Infection Prophylaxis in Pediatric Acute Myeloid Leukemia (Pro-Teico study)
An open-label, randomized clinical trial on teicoplanin infection prophylaxis in pediatric patients with acute myeloid leukemia

Justificación

No aportado

Objetivo Principal

For safety run in phase: To assess the safety of i.v. teicoplanin prophylaxis three times per week with a two to three days interval in children with newly-diagnosed AML. For randomized control phase: To evaluate whether i.v. teicoplanin prophylaxis in children with newly-diagnosed AML decreases the occurrence of culture-proven BSIs with VGS during treatment.

Variables de Evaluación Primaria

For safety run in phase: The number of DLTs observed
For the randomized controlled phase: The (first) occurrence of a culture-proven BSI with VGS during initial AML treatment
For the randomized controlled phase: Date(s) of BSI(s) with VGS.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Saftey run in phase: To (preliminary) characterize the PK parameters of teicoplanin in children with newly-diagnosed AML.
To evaluate whether i.v. teicoplanin prophylaxis in children with newly-diagnosed AML decreases the occurrence of any culture-proven bacterial BSI during treatment
To assess the impact of teicoplanin prophylaxis on the number of intensive care admissions during initial AML treatment
To assess the frequency of infectious-related morbidity and infection-related mortality
To evaluate whether i.v. teicoplanin prophylaxis affects neutrophil recovery time
To assess the development of teicoplanin-related bacterial resistance in (routine) surveillance cultures and breakthrough infections
To assess the safety and adverse events (AEs) of teicoplanin prophylaxis, with special interest regarding nephrotoxicity, ototoxicity, allergic, infusion-related or anaphylactic reactions to teicoplanin administration, sepsis with teicoplanin-resistant organisms, and the occurrence of teicoplanin-resistant organisms in routine surveillance cultures
To study if there is a confounding effect of the use of other antibiotics (e.g., fluoroquinolones) on the occurrence of culture-proven (VGS) bacterial BSIs during treatment
To assess PK parameters and construct a population PK model of teicoplanin in children with AML
To study the potential effect of co-variables on teicoplanin clearance in children treated for AML, including renal function, age, and co-medication
To study associations between serum levels of teicoplanin and the occurrence of culture-proven (VGS) bacterial BSIs during treatment
To describe the durability of response and long-term follow-up, the cumulative incidence of relapse (CIR) after achieving response, event-free survival (EFS) and overall survival (OS).

Variables de Evaluación Secundaria

Safety run in phase: PK parameters of teicoplanin, e.g., o Css,max o Css,min o Tss,max o Area under the curve o Clearance (inter-compartmental, total, renal fraction) o Volume of distribution (central and peripheral)
The number of BSIs with culture-proven bacteria; o Results of all positive blood cultures
Infection-related (pediatric) intensive care admissions; o Days at the intensive care
The number of episodes/admissions with (neutropenic) fever; o Days with fever (with or without neutropenia) o Days with FN oDays with neutropenia
Infection-free survival time, i.e., time from diagnosis to the first culture-proven BSI
Infection-related mortality
Number of days until neutrophil recovery (ANC of 0.5 x109/L following the nadir)
Resistance patterns of pathogenic isolates from blood cultures
Incidence of resistant bacteria in rectal swabs: o VRE
Incidence of resistant bacteria in (routine) surveillance cultures; throat and rectal swabs, e.g.,; o Gram-negative staphylococci o Hemolytic streptococci o Staphylococcus aureus o Fungi o Yeasts o Haemophilus influenza (only throat swab) o Pneumococci (only throat swab)
AEs of special interest, i.e.; o Grade 3 or 4 increases in serum creatinine o Grade 3 or 4 hearing impairment o Grade 3 or 4 allergic or infusion-related reaction to teicoplanin administration o Grade 3 or 4 anaphylactic reaction to teicoplanin administration o Grade 3 or 4 sepsis with teicoplanin-resistant organisms o The occurrence of teicoplanin-resistant organisms in routine surveillance cultures
Serious adverse events (SAEs)
Use of (other) antibiotics, antifungals and antivirals
PK parameters of teicoplanin, e.g.,; o Css,max o Css,min o Tss,max o Area under the curve o Clearance (inter-compartmental, total, renal fraction) o Volume of distribution (central and peripheral)
Serum creatinine levels
Serum levels of teicoplanin
Duration of response (time between achieving complete remission (CR) after starting study treatment and documented relapse or death);
CIR (Cumulative incidence of relapse)
EFS (Event-free survival)
OS (Overall survival)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Newly diagnosed with AML
Being registered and starting treatment according to the NOPHO-DBH AML 2012 study protocol, or a consecutive protocol
Age 0-19 years
Written informed consent by the patient and/or legal guardians (whatever applicable according to the patients age)

Criterios de Exclusión

Acute promyelocytic leukemia Patients that are participating in another clinical study with an IMP, that interferes with the study objectives Secondary AML Down Syndrome Preexisting primary immunodeficiency Patients who receive regular antibiotic prophylaxis against Gram-positive bacteria for other conditions than leukemia-related Patients with

a history of an anaphylactic reaction (CTCAE1 grade 3) to teicoplanin and/or vancomycin Patients with an eGFR49 of <30 ml/min/1.73m2 at the start of the study Patients with a history of severe impaired hearing (CTCAE1 grade 3) Pregnant or breast-feeding patients

Calendario

(Última actualización: 13/01/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
07/11/2022	30/03/2023	07/09/2023	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

Prinses Maxima Centrum voor Kinderoncologie B.V. Netherlands

Heidelberglaan 25

Contact Person

Secretary TDC

0889727272

TDCsecretary@prinsesmaximacentrum.nl

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

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ceim_hgua@gva.es

965913921-965913948

Centros

Activo (27/06/2023)

HOSPITAL GENERAL UNIVERSITARIO DR. BALMIS

Alicante/Alacant

ALICANTE

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

Oncohematologia Pediatrica

Activo (27/06/2023)

HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESUS

Madrid

MADRID

Activo (13/07/2023)

HOSPITAL UNIVERSITARI SON ESPASES

Palma

BALEARES

Activo (27/06/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (27/06/2023)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Activo (27/06/2023)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hospital Materno Infantil

Activo (27/06/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

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

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Hematology

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

Universidade De Santiago De Compostela

Santiago De Compostela

CORUÑA

Unidad de Hematología y Oncología Infantil

Medicamentos

Targocid 400mg powder for solution for injection/infusion or oral solution
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Código ATC: J01XA02 - TEICOPLANINA
Principios Activos: N/A

Experimental

Targocid 400mg powder for solution for injection/infusion or oral solution
SOLUTION FOR INJECTION/INFUSION
INTRAVENIOUS INFUSION

Código ATC: J01XA02 - TEICOPLANINA
Principios Activos: N/A

Experimental

Targocid 400mg powder for solution for injection/infusion or oral solution
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INTRAVENOUS

Código ATC: J01XA02 - TEICOPLANINA
Principios Activos: N/A

Experimental

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SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

Código ATC: J01XA02 - TEICOPLANINA
Principios Activos: N/A

Experimental

Sin resultados

Teicoplanin as Infection Prophylaxis in Pediatric Acute Myeloid Leukemia (Pro-Teico study)

State	**Type of participants**	**Age Ranges**
Recruiting	Incapable subjects of giving consent	Less than 18 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	40
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	prophylaxis, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-506546-23-00 (CTIS)

Protocol Code
SP_MH19PRO

Transitioned 2020-000508-13

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

Investigated Disease
Acute myeloid leukemia

Scientific Title
Teicoplanin as Infection Prophylaxis in Pediatric Acute Myeloid Leukemia (Pro-Teico study)
An open-label, randomized clinical trial on teicoplanin infection prophylaxis in pediatric patients with acute myeloid leukemia

Rationale

Not provided

Main Objective

For safety run in phase: To assess the safety of i.v. teicoplanin prophylaxis three times per week with a two to three days interval in children with newly-diagnosed AML. For randomized control phase: To evaluate whether i.v. teicoplanin prophylaxis in children with newly-diagnosed AML decreases the occurrence of culture-proven BSIs with VGS during treatment.

Primary Endpoints

For safety run in phase: The number of DLTs observed
For the randomized controlled phase: The (first) occurrence of a culture-proven BSI with VGS during initial AML treatment
For the randomized controlled phase: Date(s) of BSI(s) with VGS.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Saftey run in phase: To (preliminary) characterize the PK parameters of teicoplanin in children with newly-diagnosed AML.
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Secondary Endpoints

Safety run in phase: PK parameters of teicoplanin, e.g., o Css,max o Css,min o Tss,max o Area under the curve o Clearance (inter-compartmental, total, renal fraction) o Volume of distribution (central and peripheral)
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Duration of response (time between achieving complete remission (CR) after starting study treatment and documented relapse or death);
CIR (Cumulative incidence of relapse)
EFS (Event-free survival)
OS (Overall survival)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Newly diagnosed with AML
Being registered and starting treatment according to the NOPHO-DBH AML 2012 study protocol, or a consecutive protocol
Age 0-19 years
Written informed consent by the patient and/or legal guardians (whatever applicable according to the patients age)

Exclusion criteria

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a history of an anaphylactic reaction (CTCAE1 grade 3) to teicoplanin and/or vancomycin Patients with an eGFR49 of <30 ml/min/1.73m2 at the start of the study Patients with a history of severe impaired hearing (CTCAE1 grade 3) Pregnant or breast-feeding patients

Calendar

(Last Update: 13/01/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
07/11/2022	30/03/2023	07/09/2023	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

Prinses Maxima Centrum voor Kinderoncologie B.V. Netherlands

Heidelberglaan 25

Contact Person

Secretary TDC

0889727272

TDCsecretary@prinsesmaximacentrum.nl

Monetary support: N/A

Sponsor type: No commercial

Ceim

CEIm Departamento de Salud de Alicante- Hospital General

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Sites

Active (27/06/2023)

HOSPITAL GENERAL UNIVERSITARIO DR. BALMIS

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

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HOSPITAL UNIVERSITARIO LA PAZ

Madrid

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Active (27/06/2023)

HOSPITAL UNIVERSITARIO MIGUEL SERVET

Zaragoza

ZARAGOZA

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hospital Materno Infantil

Active (27/06/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

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

Sant Joan De Deu Barcelona Hospital

Esplugues De Llobregat

BARCELONA

Hematology

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

Universidade De Santiago De Compostela

Santiago De Compostela

CORUÑA

Unidad de Hematología y Oncología Infantil

Medication

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ATC code: J01XA02 - TEICOPLANINA

Active Principles: N/A

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ATC code: J01XA02 - TEICOPLANINA

Active Principles: N/A

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SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS

ATC code: J01XA02 - TEICOPLANINA

Active Principles: N/A

Experimental

No results