

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

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

Safety 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 o Days 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 $0.5 \times 10^9/L$ 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 07/11/2022	Inicio de Ensayo 30/03/2023	Inclusión Primer Paciente 07/09/2023	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	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

Secretary TDC

0889727272

TDCsecretary@prinsesmaximacentrum.nl

Monetary support: N/A

Tipo de promotor: No comercial

Ceim

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C/ Pintor Baeza, 12, planta 5ª Centro de Diagnósticos 03010 Alicante

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 Oncohematología Pediátrica
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

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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

Recruiting

Type of participants

Incapable subjects of giving consent

Age Ranges

Less than 18 , Adults (18-64 years)

Gender

Both

Phases

Phase III

Expected Participants

40

Results

No results

Low level of intervention

No

Rare disease

Yes

Geographic coverage

Undetermined

Areas of the study

prophylaxis, safety, effectiveness,
pharmacokinetics

Advanced therapy

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

Safety 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 C_{ss,max} o C_{ss,min} o T_{ss,max} o Area under the curve o Clearance (inter-compartmental, total, renal fraction) o Volume of distribution (central and peripheral)

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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

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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)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 13/01/2026)

Authorization 07/11/2022	Start of Trial 30/03/2023	First patient inclusion 07/09/2023	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) 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

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Sites

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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

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

SOLUTION FOR INJECTION/INFUSION

INTRAVENOUS

ATC code: J01XA02 - TEICOPLANINA

Active Principles: N/A

Experimental

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INTRAVENOUS

ATC code: J01XA02 - TEICOPLANINA

Active Principles: N/A

Experimental

No results