A population PK study into teicoplanin in intensive care and haematology patients * a strategy towards model informed precision dosing (PLATO)

Published: 30-11-2020
Last updated: 08-04-2024

To develop a population pharmacokinetic model of teicoplanin in Intensive Care and Haematology patients for the purpose of dose individualization using therapeutic drug monitoring.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49412

Source
ToetsingOnline

Brief title
PLATO

Condition

- Bacterial infectious disorders

Synonym
Bacteriele infectie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Critically ill, Model informed precision dosing, Pharmacokinetics, Teicoplanin

Outcome measures

Primary outcome

To develop a population pharmacokinetic model of teicoplanin in Intensive Care

and Haematology patients

Secondary outcome

- To estimate the influence of renal function on the teicoplanin clearance

using different renal biomarkers.

- To investigate the impact of serum albumin on bound and unbound teicoplanin

concentrations.

- To develop a limited sampling strategy for estimating the area under the

concentration time curve of teicoplanin.

Study description

Background summary

Infections with coagulase-negative staphylococci (CNS) or methicillin resistant and susceptible Staphylococcus aureus (MRSA/MSSA) strains indicates poor prognosis and increased mortality. The glycopeptides teicoplanin and vancomycin are drugs of first choice for treatment of selected gram positive infections. Outbreaks of infection with multi-drug resistant bacteria plague modern ICUs. To eradicate these strains successfully without development of resistance, optimized dosing is pivotal. Wide application of high dosage of vancomycin limit its use as high exposure is associated with nephrotoxicity in up to 20%

of the patients. Teicoplanin seems to be able to replace vancomycine as the best candidate to fight infections with CNS,
MSSA and MRSA, as it is considered equipotent to vancomycin, but associated with less drug-induced nephrotoxicity.
Therapeutic drug monitoring (TDM) is currently not routine practice with teicoplanin, despite the fact that it has been shown that long-term treatment at suboptimal concentrations of teicoplanin is a risk factor for emergence of de-novo glycopeptide-resistant strains. In conjunction it will limit toxicity due to toxic concentrations.
To optimize teicoplanin dosing we have to gain knowledge on the pharmacokinetics of teicoplanin in critically ill patients and to characterize the influence of renal function on exposure.

Study objective

To develop a population pharmacokinetic model of teicoplanin in Intensive Care and Haematology patients for the purpose of dose individualization using therapeutic drug monitoring.

Study design

Prospective, observational, pharmacokinetic study

Study burden and risks

We consider the extra burden from participating in the planned study negligible. The extra intervention compared to routine care consits os sampling a minimum amount of extra blood. A peripheral catheter is placed, which is in place during the course of the study, so that repeated puncture is not necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The patient is admitted to the ICU of the haematology department
2. The patient is at least 18 years of age on the day of inclusion
3. Is treated with teicoplanin as a part of standard care
4. Is able and willing to sign the Informed Consent form

Exclusion criteria

1. Has previously participated in this study
2. Patient receives any form of RRT other than continuous venovenous hemofiltration (CVVH).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2019
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75069.091.20
Other	PLATO

Study results

Date completed:	19-10-2021
Actual enrolment:	30

Summary results

Trial is onging in other countries