Evaluation of a new Dutch vancomycin dosage guideline in preterm and term neonates.

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

Summary

ID

NL-OMON42496

Source
ToetsingOnline

Brief title
VancoNEO

Condition

- Bacterial infectious disorders

Synonym
Antibiotic treatment

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dosing guideline, Term and preterm neonates, Vancomycin

Outcome measures

Primary outcome

Main study parameter is the number of therapeutic first vancomycin trough levels, when receiving the earlier mentioned starting doses. Furthermore, the number of sub- and supra-therapeutic first trough levels will be determined as well.

Secondary outcome

Secondary study parameter is the determination of inter-patient variability in population pharmacokinetic parameters and drug exposure/MIC, expressed as AUC/MIC. Availability of these parameters will allow further improvement of the dosage regimens.

Study description

Background summary

A recent retrospective study performed within the AMC demonstrated that the previously used vancomycin doses for term and preterm neonates possibly produces subtherapeutic serum concentrations in the majority of these patients. Conclusions were based on retrospective chart data from a limited number of cases. Based on this report and other (sparse) evidence of suboptimal vancomycin dosing, a new pediatric Vancomycin dosing schedule was introduced on the Dutch Kinderformularium website in May 2015. The Academic Medical Center, Emma Children*s Hospital has adopted this national dosing guideline. However, as even the rationale for this national dosing guideline is under debate and well-designed prospective PKPD studies are lacking. We will prospectively investigate the first therapeutic vancomycin trough concentrations in a cohort of consecutive neonatal cases receiving the adapted doses.

Study objective

The main objective of this study is to determine the number of therapeutic first trough levels (vancomycin serum concentrations between 10 and 15 mg/L), as well as subtherapeutic (serum concentrations < 10 mg/L) and supratherapeutic (serum concentrations > 15 mg/L) first trough levels, when receiving the new dosing regimens. Five categories of cases will be studied:
I: premature < 1 week,
II: premature 1 - 4 weeks,
III: term neonate < 1 week,
IV: term neonate 1 - 4 weeks,
V: infants > 1 month.
The secondary objective of this study is the determination of inter-patient variability in pharmacokinetic parameters and drug exposure, expressed as area under the curve/minimum inhibitory concentration (AUC/MIC).

Study design

This is a prospective and observational study with use of clinically scheduled blood level measurements and possible additional measurements in blood samples obtained from left over material.

Study burden and risks

The first trough serum vancomycin concentration will be determined 30 minutes prior to the 5th dose according to clinical TDM routine.
Clinically scheduled blood samples will be obtained from either indwelling arterial catheters or from venous blood sampling procedures. This is routine practice at the NICU. Leftover material from other samples will be used for the additional 3 samples and will be sent to the pharmacy laboratory for possible additional plasma level investigations. In total, 4 blood samples are needed to attain a correct population pharmacokinetic profile. Of these 4, 1 sample is obtained by clinical routine and the other 3 by investigating leftover material from other clinically indicated blood samples. The risk for the subjects is negligent. There will be no interventions performed outside the normal clinical routine.
This study will generate information regarding the adequacy of the existing and new dose regimens of vancomycin in term and preterm neonates, as well as pharmacokinetic parameters for this specific group of newborn patients. The availability of these population pharmacokinetic parameters is of clinical benefit, as it will further improve the vancomycin dosing regimens for this fragile population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Treatment with vancomycin i.v. starting dose according to hospital guidelines (table 1) for a clinically suspected or proven infection
- Signed informed consent from parents or legal guardians

Exclusion criteria

- Parent refusal
- Inability to monitor drug levels during treatment
- Inability to sample blood

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL53649.018.15