Evaluation of a new vancomycin dosage guideline in pediatric oncology patients.

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To determine the number of therapeutic first trough levels (vancomycin serum concentrations between 10 and 15 mg/L), when receiving a starting dose of 90 mg/kg/day. Furthermore, the number of subtherapeutic (serum concentration < 10 mg/L) and...

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

Summary

ID

NL-OMON40472

Source
ToetsingOnline

Brief title
Vancomycin dosing in pediatric oncology patients.

Condition

- Bacterial infectious disorders

Synonym
Antibioticum therapie

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, Pediatric oncology, Vancomycin

Outcome measures

Primary outcome

Main study parameter is the number of the therapeutic first vancomycin trough levels, when receiving a dose of 90 mg/kg/day. Furthermore, the number of sub- (< 10 mg/L) and supratherapeutic (> 15 mg/L) first trough levels is determined as well.

Secondary outcome

Secondary study parameters are the population pharmacokinetic parameters in these patients, which include both average values of clearance and volume of distribution and their intra- and interpatient variability.

Study description

Background summary

A recent retrospective study performed within the AMC demonstrated that a dose of 60 mg/kg/day vancomycin produces subtherapeutic serum concentrations in a majority of the pediatric oncologic patients. On basis of this data, pediatric oncologists of AMC have increased the vancomycin starting dose to 90 mg/kg/day. In this study we will determine the number of first therapeutic vancomycin trough concentrations, when receiving a starting dose of 90 mg/kg/day.

Study objective

To determine the number of therapeutic first trough levels (vancomycin serum concentrations between 10 and 15 mg/L), when receiving a starting dose of 90 mg/kg/day. Furthermore, the number of subtherapeutic (serum concentration < 10 mg/L) and supratherapeutic (serum concentration > 15 mg/L) trough serum concentrations are determined as well. The secondary objectives of this study are the assessment of population pharmacokinetic parameters.

Study design

This is a prospective observational cohort study with invasive measurements. The patients will receive a vancomycin starting dose of 90 mg/kg/day. On basis of clinical routine 1 trough concentration will be determined on which the dose will be adjusted, if needed. If the first trough level is not within the reference level (10 * 15 mg/L) a dosage advice is provided by the hospital pharmacist. A second trough concentration will then be determined to confirm the dosage advice. For this study, a maximum of 3 extra blood samples (3 times 50 microlitre) will be obtained. These samples may be obtained either from leftover blood from other samples or via finger pricks.

Study burden and risks

The burden of this study includes a maximum of three finger pricks to obtain three extra blood samples. If possible leftover blood from other samples will be used instead. In total, 4 blood samples are needed to attain population pharmacokinetic profile, of which one or two are obtained by clinical routine sampling. The risk for the subjects is low.
This study will generate information regarding the adequacy of the new dose regimen of vancomycin in pediatric oncology patients. The availability of the population pharmacokinetic parameters is of benefit for the future improvement of the vancomycin dosing regimen in this specific population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age 1 - 18 years
- Treatment with vancomycin i.v. for a clinically suspected or proven (catheter-related) infection
if age < 12 year: starting dose of 90 mg/kg/day (± 10%) divided in 4 doses, if age 12-18 year: starting dose of 60 mg/kg/day (± 10%) divided in 4 doses
- Diagnosed with a malignant disease for which treatment with chemotherapy is started
- Signed informed consent

Exclusion criteria

- Inability to monitor drug levels during treatment
- Kidney function test (serum creatinine): 2x ULN (upper limit of normal)

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):	24-06-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-08-2014
Application type:	Amendment
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	NL44191.018.13