The clinical validation of a dried blood spot method for vancomycin and creatinine

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The objective of this study is to clinically validate a DBS method for vancomycin and creatinine, using a LC-MS/MS method.

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

Summary

ID

NL-OMON54384

Source
ToetsingOnline

Brief title
ADVANCED study

Condition

- Bacterial infectious disorders

Synonym
concentration of antibiotic in blood following infection

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Erasmus Efficiency Grant

Intervention

Keyword: Creatinine, Dried blood spot analysis, Therapeutic drug monitoring, Vancomycin

Outcome measures

Primary outcome

To clinically validate the DBS method for vancomycin and creatinine in

comparison to venipuncture vancomycin and creatinine analysis

Secondary outcome

- Analyzing the differences in the measured concentrations in the dried blood

spot made with blood obtained from venous sampling and capillary sampling.

- Evaluating the need of a correction factor and optimizing the correction

factor when measuring the hematocrit in the DBS samples

- To investigate the patients* experience with the DBS method in comparison to

venipuncture

Study description

Background summary

The OPAT service consists of providing antimicrobial therapy by parenteral infusion without hospitalization. A widely used antibiotic in OPAT is vancomycin. To ensure adequate exposure to vancomycin, drug doses are adjusted based on whole-blood concentration measurements, a practice known as therapeutic drug monitoring (TDM). The need for TDM of vancomycin is well established, as described in several national and international guidelines, for dose-optimization in order to achieve successful treatment and to prevent toxicity and reduce microbial resistance. A drawback of vancomycin use in OPAT is the need for laboratory monitoring of vancomycin which requires patients to travel to a blood sampling facility for blood sampling. A sampling method for TDM that has become more popular over the recent years is dried blood spotting (DBS). DBS is a design of blood sampling consisting of positioning a drop of capillary blood, preferably taken from the finger, on filter paper. Unlike venous blood sampling (the current gold standard for TDM of vancomycin), DBS

seems to have advantages for the patient. The finger prick is less invasive than venipuncture. DBS also enables patients to perform one or multiple finger prick(s) themselves, which may result in less frequent hospital visitations and the possibility to sample at multiple time points. Due to the fact that vancomycin is nephrotoxic, it would be very efficient and convenient to measure creatinine in the same dried blood spot as the vancomycin.

Study objective

The objective of this study is to clinically validate a DBS method for vancomycin and creatinine, using a LC-MS/MS method.

Study design

Cross-sectional observational study.

Study burden and risks

Participants will undergo one fingerprick (approximately 550 microliters blood will be drawn), which causes mild irritation, and are asked to fill in a short questionnaire.

An additional cohort of n=20 patients will be included to validate the correction formula for vancomycin and creatinin. These patients will undergo one fingerprick and are asked to fill in a short questionnaire.

In future, this DBS method can be used in clinical practice, which uses less blood volume for therapeutic drug monitoring and can be applied by the patient at home.

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

- Aged 18 and over
- Able to understand written information and able to give informed consent
- Treated with vancomycin
- Able and willing to undergo a finger prick for dried blood spot sampling
- Able and willing to fill in a questionnaire

Exclusion criteria

unable to draw blood samples for study purposes

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	21-03-2022
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	23-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL79269.078.21