A Dried blood spot sampling method for VANcomycin and Creatinine monitoring: Effectiveness Demonstrated in Outpatient Parenteral Antibiotic Therapy service

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To investigate if dried blood spot sampling of vancomycin and creatinine leads to less outpatient visits regarding vancomycin therapy compared to conventional sampling in OPAT service.

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

Summary

ID

NL-OMON53282

Source
ToetsingOnline

Brief title
ADVANCED OPAT

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 sampling, Therapeutic drug monitoring, Vancomycin

Outcome measures

Primary outcome

The main study parameter is the amount of outpatient visits regarding

vancomycin therapy.

Secondary outcome

Outcomes regarding outpatient visits

- To compare the amount of outpatient visits with the sole purpose of

vancomycin TDM in the control group versus intervention group (phlebotomy

visits)

- To compare the amount of outpatient visits with the sole purpose of

laboratory sampling (with and without TDM) in the control group versus

intervention group

- To compare the amount of outpatient visits regarding vancomycin therapy

without laboratory sampling in the control group versus intervention group

- To compare the amount of outpatient visits regarding vancomycin therapy

including laboratory sampling (with and without TDM) in the control group

versus intervention group

- To compare the amount of VNC therapy related telephone consultations in the

control group versus intervention group

Sampling outcomes

- To compare the amount of correct blood sampling in the control group versus intervention group
- To investigate the DBS sampling quality
- To investigate how many patients are failing DBS (and are subsequently switched to conventional blood sampling)
- To explore the facilitators and barriers for (in)correct DBS sampling
- Amount of patients unable to perform fingerprick after training in the hospital
- To explore potential determinants for patients who are failing or passing DBS sampling under supervision after training (determinants taken into account are e.g. demographic factors (age, sex, weight), use of anticoagulans, sampling by patient or by family member/caregiver)

Satisfaction and quality of life outcomes

- To investigate if dried blood spot sampling of vancomycin leads to a higher patient satisfaction compared with conventional sampling in OPAT service.
- To explore potential determinants for patient satisfaction; determinants taken into account are e.g. demographic factors (age, sex, weight), geographic factors (distance to sampling facility, mode of transportation to sampling facility), medical factors (treatment infection, comorbidities, duration of antibiotic treatment, outpatient visits, time to discharge), sampling factors (DBS sampling by patient or by family member/caregiver, conventional sampling by venepuncture or by drawing blood from line), patient costs and costs related

to loss of productivity.

- To investigate if dried blood spot sampling of vancomycin leads to a higher quality of life compared with conventional sampling in OPAT service.

Cost outcomes

- To compare patient costs in the control group versus intervention group
- To compare costs related to loss of productivity in the control group versus intervention group
- To compare health care costs in the control group versus intervention group
- To compare societal costs (total of all costs) in the control group versus intervention group

Clinical outcomes

- To compare clinical outcomes (e.g. reinfection, readmission, complications, duration of treatment, mortality) in the control group versus intervention group
- To compare the relative amount of nephrotoxicity occurrence (defined as in the RIFLE criteria) in the control group versus intervention group
- To compare the time to discharge after signing up for OPAT in the control group versus intervention group
- To compare the duration of hospital stay in the control group versus intervention group

TDM outcomes

- To compare the relative amount of creatinine measurements in the control group versus intervention group

- To compare the relative amount of vancomycin measurements in the control group versus intervention group

- To compare the relative time of vancomycin levels in the therapeutic range in the control group versus intervention group

- To compare the amount of dosage changes of vancomycin therapy in the control group versus intervention group

- To compare the time to achieving the therapeutic range of vancomycin levels after dosage changes in the control group versus intervention group

Logistical outcomes

- To compare the time of vancomycin blood sample arrival at the lab after sampling in the control group versus intervention group

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 blood concentration measurements, a practice known as therapeutic drug monitoring (TDM). A drawback of vancomycin use in OPAT is the need TDM which requires patients to travel to a blood sampling facility for blood sampling. An alternative sampling method for TDM is the dried blood spot (DBS) method (i.e. a finger prick). OPAT is provided for patients who are stable and healthy enough to leave the hospital and clinical monitoring of these patient population is minimal. However, clinical monitoring of vancomycin therapy during OPAT is intensive due to TDM of vancomycin. By implementing DBS sampling the amount of clinical consultations regarding vancomycin therapy in OPAT

services can be reduced. Furthermore, this effectiveness may increase when a biochemical parameter such as renal function parameter (i.e. creatinine) are measured along with drug concentrations (leading to even less outpatient visits); the benefit of this has not been investigated yet

Study objective

To investigate if dried blood spot sampling of vancomycin and creatinine leads to less outpatient visits regarding vancomycin therapy compared to conventional sampling in OPAT service.

Study design

Open label randomized controlled parallel study.

Study burden and risks

All patients in both arms will receive standard of care treatment with vancomycin and perform therapeutic drug monitoring of vancomycin as usual. The only difference in the intervention arm is that blood sampling is performed by dried blood spot sampling at home after being trained in the hospital. If dried blood spot sampling fails, patients will be asked to go to a phlebotomy facility for blood drawing (traditional sampling). Some patients in the intervention group will be interviewed. All patients will be asked to fill out questionnaires about medical consumption, work, satisfaction and quality of life. Patients in the intervention arm may benefit from this study as the need for travelling to a blood drawing facility is no longer required.

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
- Hospitalized
- Treated with intravenous vancomycin and to be discharged with vancomycin OPAT service with minimal 1 planned outpatient vancomycin TDM order
- Able and willing to perform finger pricks for dried blood spot sampling, or able and willing to undergo finger pricks performed by family members or other caregivers
- Able and willing to fill in questionnaires

Exclusion criteria

- Former participation in this trial
- Cognitive dysfunction or other dysfunctionalities which makes the patient unable to draw blood by a fingerprick or fill out questionnaires
- Unable to sample an adequate DBS after training in the hospital (this is also applicable for family members or other caregivers who are failing to perform adequate DBS sampling for the patient)

Study design

Design

Study type: Observational invasive

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-04-2023
Enrollment:	88
Type:	Anticipated

Ethics review

Approved WMO Date:	06-07-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-11-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-05-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2024
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	NL83813.078.23