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

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

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56304

Source
ToetsingOnline

Brief title
VIDA study

Condition

- Other condition

Synonym
Concentrations of drugs in blood following transplantation

Health condition

Transplantatie

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

Intervention

Keyword: Creatinine, Dried blood spot analyse, Immunosuppressiva, Therapeutic drug monitoring

Outcome measures

Primary outcome

Correlation between the DBS concentrations and venous blood concentrations of

immunosuppressive drugs and creatinine.

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 when measuring the hematocrit in

the DBS samples

- Analyzing the difference between the drug concentration in the microtainer

and filtrate card, to investigate the influence of the filtrate card on the

drug concentration

Study description

Background summary

Transplant rejections can occur when a patient is not properly adjusted on immunosuppressive drugs. To ensure adequate exposure to immunosuppressive drugs, drug doses are adjusted based on whole-blood concentration measurements, a practice known as therapeutic drug monitoring (TDM). A sampling method for TDM that has become more popular over the recent years is dried blood spotting (DBS). Unlike venous blood sampling (the current gold standard for TDM

immunosuppressive drugs), DBS seems to have advantages for the patient. Due to the fact that the cornerstone of immunosuppression, tacrolimus, everolimus, sirolimus and ciclosporin are nephrotoxicity and are prescribed to maintain adequate kidney transplant function, it would be very efficient and convenient to measure creatinine in the same dried blood spot as the immunosuppressants. This method uses less blood volume and can be applied at home by the patient himself.

Study objective

The objective of this study is to clinically validate a DBS method for immunosuppressive drugs 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 tacrolimus. These patients will undergo one fingerprick.
An additional cohort of n=80 patients will be included to validate the optimized method of tacrolimus and cyclosporine. These patients will undergo one fingerprick.

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)

Inclusion criteria

- Aged 18 and over
- Able to understand written information and able to give informed consent
- Treated with tacrolimus, everolimus, sirolimus and/or ciclosporin
- 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):	06-04-2020
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	01-04-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-05-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2024
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	NL72082.078.19