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

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Concentration of immunosuppressive drugs and creatinine could be measured using dried blood spot

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23332

Bron
Nationaal Trial Register

Verkorte titel
VIDA study

Aandoening

Transplant recipients

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Optimizing the correction factor needed and clinically validating a DBS method for

tacrolimus, everolimus, sirolimus, ciclosporin and creatinine.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Transplant rejections can occur when a patient is not properly adjusted on immunosuppressive drugs. The great interpatient pharmacokinetic variability of immunosuppressive drugs, can lead to under- and overexposure with serious consequences. 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). 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 immunosuppressive drugs), 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 the cornerstone of immunosuppression, tacrolimus, everolimus, sirolimus and ciclosporin are nephrotox 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.
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 population: Forty patients aged 18 or over, will be included for each of the four drugs, (tacrolimus, everolimus, sirolimus and ciclosporin), i.e. 160 patients in total.
Intervention (if applicable): Patients are treated with tacrolimus, everolimus, sirolimus or ciclosporin, in the dose prescribed by their treating physician. In addition to the standard venous samples, DBS samples will be collected by a trained student or nurse from patients visiting the hospital for periodic check-ups.
Main study parameters/endpoints: Correlation between the DBS concentrations and venous blood concentrations of immunosuppressive drugs and creatinine.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: After receiving informed consent from the patients, a finger prick for both the filtrate paper and microtainer will be performed in addition to the standard venipuncture. A finger prick carries a minimal risk of complications. This intervention may cause mild pain or local irritation. During the study, the participating patients will have no benefits. The blood samples will be drawn by a nurse or trained researcher during regular hospital visits. Secondly, after the collection of the blood samples a short questionnaire will be taken, with four questions, assessing the patients' experience of the DBS method in comparison to venipuncture. When the method is successfully validated, DBS may be of great benefit to a larger group of patients that use immunosuppressive drugs.

Doel van het onderzoek

Concentration of immunosuppressive drugs and creatinine could be measured using dried blood spot

Onderzoeksopzet

Predose level

Onderzoeksproduct en/of interventie

Patients are treated with tacrolimus, everolimus, sirolimus or ciclosporin, in the dose prescribed by their treating physician. In addition to the standard venous samples, DBS samples will be collected from patients visiting the hospital for periodic check-ups.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unable to draw blood samples for study purposes

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-04-2020
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8502
Ander register	METC Erasmus MC : MEC-2019-0783

Resultaten