A randomized controlled trial comparing Dried Blood Spot sampling to venous sampling for Therapeutic Drug Monitoring in tacrolimus using kidney transplant patients: a cost minimization analysis.

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To determine the difference in the amount (average per patient) of clinical check-ups performed in the hospital for the DBS and the non-DBS group. To compare the total economic burden for the intervention and non-intervention groups from a societal...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43269

Source
ToetsingOnline

Brief title
Cost minimization analysis of Dried Blood Spots

Condition

- Other condition

Synonym
Kidney transplantation, Solid organ transplantation

Health condition

Niertransplantatie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw

Intervention

Keyword: Cost analysis, Dried Blood Spot (DBS), Therapeutic Drug Monitoring, Transplantation

Outcome measures

Primary outcome

Amount of patient visits to the policlinic of the UMCG for a scheduled check-up

as reported in the Electronic Patient Dossier (EPD).

Secondary outcome

•Prescriptions written and printed for the immunosuppressant tacrolimus and

given to the patient and/or faxed to the community pharmacy and/or general

practitioner.

•Time spent by the nephrologist preparing and finishing a patients* visit at

the policlinic including phone calls.

•Intra individual variation in tacrolimus trough blood concentration between

the DBS and non-DBS group

•Loss in worktime for attending check-ups at the policlinic of the UMCG

•Satisfaction and feasability of DBS

Study description

Background summary

Immunosuppressants such as Tacrolimus (TaC) are successfully applied in solid organ transplantation to prevent allograft rejection. Because of their narrow therapeutic range and significant inter- and intra-individual variability in absorption and metabolism, therapeutic drug monitoring (TDM) is important in the clinical follow-up of immunotherapy receiving transplant patients to balance between subtherapeutic and toxic effects of these drugs. Outpatients receiving immunotherapy need to travel to the hospital on a regular basis for follow-up and to have their blood samples taken and analyzed. The results of the analysis are obtained the next day forcing the physician to call the patient and discuss dose change. With the use of Dried Blood Spots (DBS), capillary blood is obtained through a fingerprick with a lancet and is applied to a sampling card. This method is patient friendly and allows patients to sample at home and sent the DBS card to the laboratory by mail. This saves patient transportation costs and time and possibly visits to the policlinic. In addition, the monitoring results will be timely available for the clinician before patients visit the clinic for their routine check-up. To date, however, no studies have investigated the costs and effects of DBS in clinical use. Providing evidence for the cost-effectiveness of DBS may lead to a more widespread use of this technology and thus cost savings and an increase of the quality of care for the transplant patient.

Study objective

To determine the difference in the amount (average per patient) of clinical check-ups performed in the hospital for the DBS and the non-DBS group. To compare the total economic burden for the intervention and non-intervention groups from a societal perspective using cost-minimization analysis.
To determine the satisfaction of patients using dried blood spots.

Study design

prospective, randomized controlled trial.

In the DBS group, patients will undergo training in DBS sampling while they are still hospitalized. In the week prior to their routine check-ups they will perform a DBS and sent it to the laboratory of hospital pharmacy of the UMCG for analysis. The blood drug concentrations will be discussed with the patient at the check-up in the policlinic. All patients in this group will be treated according to the standard care. Four weeks after inclusion the patient will receive a questionnaire in which questions will be asked about the loss in worktime, feasibility and satisfaction of DBS.

The control group will not receive training in DBS. Blood sampling will take place in the UMCG by acquiring wholeblood through a venapuncture. The blood drug concentration will be discussed with the patient by phone or at the next check-up in the policlinic. All patients in this group will be treated according to the standard care. Four weeks after inclusion the patient will receive a questionnaire in which questions will be asked about the loss in worktime.

Intervention

Depending on randomization:
- Performing the Dried Blood Spots sampling method at home (DBS-group)
- Use conventional whole blood sampling at the UMCG (control-group)
- Filling in a questionnaire

Study burden and risks

Patients will receive standard care in either group and will have to undergo little extra proceedings. From the patients* perspective, only the training in DBS, the application of a fingerprick instead of venous blood sampling and filling in a questionnaire will be extra to the received care. There is no risk associated with either of these proceedings.

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

Age 18 years or older
Use tacrolimus
Received a kidney transplant in the UMCG and are still hospitalized
Speak the Dutch language
Are able to use the DBS sampling method

Exclusion criteria

Not able to use the DBS method
Not able to speak the dutch language

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-10-2016

Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	17-05-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22997
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL56927.042.16
OMON	NL-OMON22997