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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22997

Source
Nationaal Trial Register

Brief title
CMA DBS

Health condition

Kidney transplantation

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Astellas Pharma Ltd, ZonMw

Intervention

Outcome measures

Primary outcome

Amount of patient visits (average per patient) to the policlinic of the UMCG for a scheduled check-up as reported in the Electronic Patient Dossier (EPD).

Secondary outcome

• To determine the difference in the amount (average per patient) of prescriptions written for tacrolimus for the DBS and the non-DBS group.
• To determine the difference in amounts of time (average per patient) a physician needs for the clinical follow-up (including phone-calls).
• To determine the difference in variation of tacrolimus blood concentration between the DBS and non-DBS group.
• To determine the loss in work time (average per patient) for attending one check-up in the policlinic.
• 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 description

Background summary

Rationale: Immunosuppressants such as Tacrolimus are successfully applied in solid organ transplantation to prevent allograft rejection. 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. 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. To date, 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.
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 and perform a cost minimization analysis.
Study design: Prospective, randomized controlled trial.
Study population: Tacrolimus using patients aged 18 years and older who are still hospitalized after receiving a kidney transplantation in the UMCG who are able to use the

DBS sampling method and speak Dutch.
Intervention (if applicable): Randomization, performing a fingerprick at home, filling in a questionnaire.
Main study parameters/endpoints: Amount of patient visits (average per patient) to the policlinic of the UMCG for a scheduled check-up as reported in the Electronic Patient Dossier (EPD).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The potential benefit of this study is the possibility to prove the cost-effectiveness of a new, patient friendly and efficient method of blood sampling for TDM in transplant patients. 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.

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 and perform a cost minimization analysis.

Study design

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Intervention

Using Dried Blood Spots prior to scheduled check-up with phycisian.

Contacts

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Eligibility criteria

Inclusion criteria

Tacrolimus using patients aged 18 years and older who are still hospitalized after receiving a kidney transplantation in the UMCG who are able to use the DBS sampling method and speak Dutch.

Exclusion criteria

Not meeting inclusion criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2016
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	07-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43269
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7721
CCMO	NL56927.042.16
OMON	NL-OMON43269

Study results