Extended trough level measurement with extended release formulation of tacrolimus

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To assess whether in renal transplant patients with tacrolimus OD taken in the morning measurement of the trough level can be delayed from the morning to the afternoon.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON34374

Source
ToetsingOnline

Brief title
Advadal

Condition

- Renal disorders (excl nephropathies)

Synonym
renal transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Astellas,Astellas Pharma

Intervention

Keyword: tacrolimus OD, trough level

Outcome measures

Primary outcome

The difference between trough levels measured at 24 hours and at 32 hours after

taking of tacrolimus OD.

Secondary outcome

The extent of correlation between these two measurements

Study description

Background summary

Tacrolimus belongs to the standard immunosuppressive drugs after renal transplantation. Tacrolimus has a narrow therapeutic window with overexposure leading to acute and chronic forms of nephrotoxicity. Therapeutic drug monitoring (TDM) is therefore commonly applied in patients who are treated with tacrolimus. In our center, like in many other centers, TDM is performed by measuring the trough level of the drug. An extended release formulation of tacrolimus has recently been introduced on the market and it offers the benefit of once-daily administration in the morning. Conversion of stable kidney transplant recipients from a twice daily regimen to tacrolimus OD indicated that they have a similar exposure (AUC) and trough levels (Cmin). When patients use tacrolimus twice daily and visit the outpatient clinic in the afternoon it is not feasible to measure the trough level. According to the product information trough level of tacrolimus OD should be measured 24 hours after taking it. However terminal elimination half life time is 37.8 hours in healthy volunteers.Theoretically, the difference between trough levels measured in the morning and in the afternoon may be small enough to be acceptable for daily clinical practice.
The current study aims to investigate whether in renal transplant patients with tacrolimus OD the blood levels of tacrolimus remain relatively stable between 24 and 32 hours after intake.

Study objective

To assess whether in renal transplant patients with tacrolimus OD taken in the

morning measurement of the trough level can be delayed from the morning to the afternoon.

Study design

This is a cross-sectional study to evaluate whether in renal transplant patients with tacrolimus OD trough levels can reliably be measured in the afternoon. To this end, the changes in trough level of tacrolimus between 24 hours and after 32 hours after intake will be determined.

Study burden and risks

There are no risks associated with participation. The burden consists of taking 11 blood samples by themselves.

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

1. Recipient of a renal graft
2. Age: 18 years or older
3. Informed consent
4. At least 2 months after renal transplantation
5. Treatment with tacrolimus OD
6. Tacrolimus trough levels within the target range (5-10 ug/l) at two subsequent occasions.

Exclusion criteria

1. Severe diarrhea (> 3 stools per day)
2. Change in tacrolimus dosage within one week prior to inclusion

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	06-01-2011

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL34158.091.10