Model based tacrolimus dosing

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23288

Source
NTR

Brief title
MOZAIEK III

Health condition

Kidney transplantation tacrolimus pharmacokinetics

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Stichting de Merel

Intervention

Outcome measures

Primary outcome

The main study endpoint of the study is the proportion of patients reaching the target C0 (7.5-12.5 ng/mL) on day 3.

Secondary outcome

Secondary study endpoints of the study are:

1: The proportion of patients reaching the target C0 (7.5-12.5 ng/mL) on day 5, 7 and 10.

2: The proportion of patients with markedly supra- (>20 ng/mL) or sub-therapeutic (<5 ng/mL) tacrolimus C0 on day 3 after transplantation.

3: The time to reach the target C0 (7.5-12.5 ng/mL).

4: Incidence of BPAR and (serious) adverse events within the first 30 days after transplantation.
5: The relationship between the intracellular tacrolimus concentration and the whole blood concentration.

Study description

Background summary

Objective: The key objective is to minimize the occurrence of subtherapeutic and supra-therapeutic C0 of tacrolimus in the immediate post-transplant phase by basing the starting dose on the dosing algorithm.

Study design: Prospective, single-arm, therapeutic intervention study
Study population: Adult kidney transplant recipients.

Intervention: All participants will receive the tacrolimus starting dose based on a dosing algorithm which takes genetic, demographic and clinical factors into account, rather than the standard bodyweight-based dose.

Main study parameters/endpoints: The main study parameter is the percentage of patients within the target C0 range of tacrolimus (7.5 to 12.5 ng/mL) on day 3 after kidney transplantation.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The extra burden is limited to one 7 mL EDTA blood sample and one 10 mL heparin blood sample for determining the intracellular tacrolimus concentration. These samples will be drawn at the same time as the regular tacrolimus blood sampling and therefore no extra vena puncture is necessary. All patients will receive identical care to those not included in the study. TDM will be performed and the tacrolimus dosage will be adjusted accordingly.

Study objective

The key objective is to minimize the occurrence of sub-therapeutic and supra-therapeutic C0 of tacrolimus on days 3, 5, 7 and 10 after transplantation by basing the starting dose of tacrolimus on a dosing algorithm, rather than the standard bodyweight-only-based approach.

Study design

Day 3, 5, 7, 10 and 30 following transplantation

Intervention

Tacrolimus starting dose based on a dosing algorithm

Contacts

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Eligibility criteria

Inclusion criteria

• Age ≥ 18 years old

• Patients receiving a kidney from a living donor (related or unrelated)

• Patients who will receive tacrolimus as part of the initial immunosuppressive therapy

• Signed written informed consent.

Exclusion criteria

• Patients receiving a kidney from a blood group AB0-incompatible donor

• Patients receiving a kidney form an HLA-incompatible donor (non-desensitized patients)

• Recipients of a non-renal organ transplant at the same occasion

• Recipients receiving immunosuppressive therapy (except steroid treatment) within the preceding 28 days.

• Recipients using medication known to have a pharmacokinetic interaction with tacrolimus.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46562
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7360
NTR-old	NTR7568
CCMO	NL64596.078.18
OMON	NL-OMON46562

Study results

Summary results
https://www.ncbi.nlm.nih.gov/pubmed/?term=andrews+LM