Avoiding tacrolimus under- and overexposure by using a dosing algorithm for pediatric renal transplant recipients

No registrations found.

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

Summary

ID

NL-OMON27765

Source
Nationaal Trial Register

Health condition

Renal transplantation
Niertransplantatie

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam, The Netherlands
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 (10-15 ng/mL) on day 3.

Secondary outcome

Secondary study endpoints of the study are:

1: The proportion of patients reaching the target C0 (10-15 ng/mL) on day 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 (10-15 ng/mL).

4: Incidence of BPAR and (serious) adverse events within the first 10 days after transplantation.

Study description

Background summary

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

- Study design: Prospective, multi-centre, single-arm, therapeutic intervention study

- Study population: Pediatric de novo 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 children within the target C0 range of tacrolimus (10-15 ng/mL) on day 3 after kidney transplantation.

- Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is no extra burden for the included children.

Study objective

The key objective is to minimize the occurrence of sub-therapeutic and supra-therapeutic C0 of tacrolimus on days 3, 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, 7 and 10 following transplantation

Intervention

Tacrolimus starting dose based on a dosing algorithm

Contacts

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Eligibility criteria

Inclusion criteria

1: Age 2-18 years old

2: Patients to be transplanted with a kidney allograft

3: Patients receiving a kidney from a blood group AB0-compatible donor

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

Exclusion criteria

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

2: Recipients of a blood group AB0-incompatible kidney allograft

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

4: Recipients using medication known to have a pharmacokinetic interaction with tacrolimus

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-11-2017
Enrollment:	28
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-12-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44606

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6694
NTR-old	NTR6864
CCMO	NL61720.078.17
OMON	NL-OMON44606

Study results

Summary results
N/A