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

Gepubliceerd: 05-12-2017 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27765

Bron
NTR

Aandoening

Renal transplantation
Niertransplantatie

Ondersteuning

Primaire sponsor: Erasmus MC, Rotterdam, The Netherlands
Overige ondersteuning: Stichting de Merel

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint of the study is the proportion of patients reaching the target C0 (10-15 ng/mL) on day 3.

Toelichting onderzoek

Achtergrond van het onderzoek

- 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.

Doel van het onderzoek

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.

Onderzoeksopzet

Day 3, 7 and 10 following transplantation

Onderzoeksproduct en/of interventie

Tacrolimus starting dose based on a dosing algorithm

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-11-2017
Aantal proefpersonen:	28
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44606
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A