Model based tacrolimus dosing

Gepubliceerd: 19-10-2018 Laatst bijgewerkt: 15-05-2024

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...

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

Samenvatting

ID

NL-OMON23288

Bron
NTR

Verkorte titel
MOZAIEK III

Aandoening

Kidney transplantation tacrolimus pharmacokinetics

Ondersteuning

Primaire sponsor: Erasmus MC
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 (7.5-12.5 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 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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Tacrolimus starting dose based on a dosing algorithm

Contactpersonen

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/

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46562
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

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