

A SINGLE-CENTER PHARMACOGENETIC STUDY OF DONOR AND RECIPIENT TO IMPROVE THE EFFICACY AND REDUCE THE NEPHROTOXICITY OF TACROLIMUS AFTER KIDNEY TRANSPLANTATION.

Gepubliceerd: 25-02-2010 Laatste bijgewerkt: 18-08-2022

N/A

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

Samenvatting

ID

NL-OMON22836

Bron

NTR

Verkorte titel

CYP3A5 for dosing tacrolimus

Aandoening

Kidney transplantation

Ondersteuning

Primaire sponsor: Erasmus Medical Center

Overige ondersteuning: Erasmus Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint of the study is the proportion of patients reaching target levels (10-15 ng/ml) on day 3 and day 7 after transplantation.

Toelichting onderzoek

Achtergrond van het onderzoek

The aims of the current study are two-fold. First we will investigate whether a CYP3A5 genotype-based tacrolimus dosing strategy will result in improved clinical outcomes as compared with a standard tacrolimus dosing regimen based on bodyweight. Second, we will investigate if ABCB1 and CYP3A5 and single-nucleotide polymorphisms (SNPs) in their encoding genes are associated with the development of tacrolimus-induced nephrotoxicity after kidney transplantation.

Doel van het onderzoek

N/A

Onderzoeksopzet

Time frame: three months.

Onderzoeksproduct en/of interventie

Patients in the standard tacrolimus dose group will receive a dose of 0.20 mg tacrolimus/kg bodyweight per day in two equally divided doses. Patients in the CYP3A5 dosing group will receive a tacrolimus dose of 0.30 mg/kg per day in two equally divided doses if they express CYP3A5 (carriers of the CYP3A5*1 allele) or will receive a tacrolimus dose of 0.15 mg/kg bodyweight in two equally divided doses if they are CYP3A5 non-expressers (CYP3A5*3 allele homozygotes). The tacrolimus dose will be adjusted according to pre-dose concentrations (C0) aiming for target concentrations of 10-15 ng/mL in weeks 1-2, 8-12 ng/mL in weeks 3 and 4 and 5-10 ng/mL thereafter.

All patients will undergo protocol biopsies at $t = 0$ (pre-implantation biopsy) and at 3 months after transplantation. The pre-implantation biopsy is routinely performed in all patients. The biopsy at 3 months is taken as part of the study protocol.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult recipients (18 years or older) who are to receive an ABO-compatible single-organ kidney transplant from a living donor (related or unrelated) will be eligible for entry into the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients receiving immunosuppressive therapy (except steroid treatment) within the preceding 28 days except for pretransplant immunosuppressive medication (up to 48 hr before transplantation) will not be included. In addition, patients using medication known to have a pharmacokinetic interaction with tacrolimus will not be asked to participate in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	25-02-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2109
4 - A SINGLE-CENTER PHARMACOGENETIC STUDY OF DONOR AND RECIPIENT TO IMPROVE THE EFFI ...	
5-05-2025	

Register

NTR-old

Ander register

ISRCTN

ID

NTR2226

METC Erasmus MC : 2010-080

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A