IMPROVEMENT OF RENAL FUNCTION BY CONVERSION OF TACROLIMUS TO EVEROLIMUS 3 MONTHS AFTER KIDNEY TRANSPLANTATION.

Gepubliceerd: 06-09-2010 Laatst bijgewerkt: 18-08-2022

The most important problem after kidney transplantation is the occurrence of chronic interstitial fibrosis (IF) and tubular atrophy (TA), which leads to graft loss. Tacrolimus induced nephrotoxicity importantly contributes to the development of IF/...

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

Samenvatting

ID

NL-OMON24603

Bron
NTR

Verkorte titel
Conversion from tacrolimus to everolimus in renal

Aandoening

Kidney transplant recipients
Tacrolimus
Everolimus
Niertransplantatie patiënten

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: Erasmus Medical Center
Novartis

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

For this conversion study renal function is the primary endpoint. Mean MDRD clearances will be compared between tacrolimus and everolimus treated patients at month 12. Also changes in MDRD clearances within individual patients in the tacrolimus and everolimus treated patients between month 3 and 12 will be compared.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

The most important problem after kidney transplantation is the occurrence of chronic interstitial fibrosis (IF) and tubular atrophy (TA), which leads to graft loss. Tacrolimus induced nephrotoxicity importantly contributes to the development of IF/TA. By converting tacrolimus maintenance therapy to everolimus the nephrotoxic side effects of this drug will be eliminated tacrolimus and renal function may be preserved.

Objective:

To investigate if conversion of tacrolimus-based immunosuppression to everolimus-based immunosuppression results in preservation of renal function as compared to continued tacrolimus-based immunosuppression. In addition to renal function also changes in renal histology following conversion of tacrolimus-based immunosuppression to everolimus-based immunosuppression will be studied.

Study design:

A randomized, controlled parallel study: At three months after transplantation patients will be randomised for continuation of tacrolimus or conversion to everolimus maintenance therapy.

Intervention:

One group will continue tacrolimus three months after transplantation and the other group will be converted to everolimus three months after transplantation.

Main study parameters/endpoints:

Renal function is the primary endpoint. Mean
glomerular filtration rate (GFR; calculated by use of the MDRD formula) will be compared between tacrolimus and everolimus treated patients at month 12. In addition, differences in MDRD GFR within individual patients in the tacrolimus and everolimus treated patients between month 3 and 12 will be compared.

Doel van het onderzoek

The most important problem after kidney transplantation is the occurrence of chronic interstitial fibrosis (IF) and tubular atrophy (TA), which leads to graft loss. Tacrolimus induced nephrotoxicity importantly contributes to the development of IF/TA. By converting tacrolimus maintenance therapy to everolimus the nephrotoxic side effects of this drug will be eliminated tacrolimus and renal function may be preserved.

Onderzoeksopzet

Month 3 after kidney transplantation.

Onderzoeksproduct en/of interventie

Conversion of tacrolimus-based immunosuppression to everolimus-based immunosuppression three months after kidney transplantation. At three months after transplantation patients will be randomized for continuation of tacrolimus or conversion to everolimus maintenance therapy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Treatment with immunosuppressive therapy consisting of tacrolimus, corticosteroids and mycophenolate mofetil at 3 months after transplantation;

2. Patients who have given written informed consent to participate in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute rejection episodes less than 4 weeks prior to randomization;

2. Proteinuria ≥ 1.0 g/day;

3. GFR ≤ 30 mL/min;

4. Recipient of multiple organ transplants;

5. Recipient of ABO incompatible allograft or a positive cross-match;

6. Patient who is human immunodeficiency virus (HIV) positive;

7. Patient who received an allograft from a Hepatitis B surface Antigen (HBsAg) or a Hepatitis C Virus (HCV) positive donor;

8. Patient with severe allergy requiring acute (within 4 weeks of baseline) or chronic treatment that would prevent patient from potential exposure to everolimus, or with hypersensitivity to drugs similar to everolimus (e.g. macrolides);

9. Patient with severe hypercholesterolemia or hypertriglyceridemia that cannot be

controlled;

10. Patient with white blood cell (WBC) count ¡Ü 2,000 /mm3 or with platelet count ≤ 50,000 /mm3;

11. Patients with ongoing wound healing problems, clinically significant infection requiring continued therapy or other severe surgical complication in the opinion of the investigator;

12. Presence of intractable immunosuppressant complications or side effects;

13. Females of childbearing potential who are planning to become pregnant, who are pregnant and/or lactating, who are unwilling to use effective means of contraception.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	25-10-2010
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2010
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	NL2436
NTR-old	NTR2545
Ander register	EudraCT : 2010-019398-14
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A