Minimization of maintenance immunosuppression early after renal transplantation.

Gepubliceerd: 06-01-2009 Laatst bijgewerkt: 18-08-2022

Chronic allograft nephropathy is the main cause of long-term renal transplant failure. The pathogenesis involves amongst others calcineurin inhibitors. We performed a multicenter randomized trial to study the effects of withdrawal of ciclosporin (...

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

Samenvatting

ID

NL-OMON22724

Bron
NTR

Verkorte titel
MECANO

Aandoening

renal transplantation, renal failure
ciclosporin, allograft nephropathy, everolimus, mycophenolate mofetyl.
Niertransplantatie, ciclosporine, cardiovasculaire bijwerkingen

Ondersteuning

Primaire sponsor: Novartis Pharma
Overige ondersteuning: Novartis Pharma

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The degree of inflammation and fibrosis and the degree of arteriolar hyalinosis in renal biopsies taken at 6 and 24 months after implantation. Biopsies will be evaluated according to the Banff ‘97 Criteria for Renal Allograft Biopsy Interpretation (appendix II). Quantitative morphometric analysis of interstitial fibrous tissue will be performed using the digital image analysis technique

Toelichting onderzoek

Doel van het onderzoek

Chronic allograft nephropathy is the main cause of long-term renal transplant failure. The pathogenesis involves amongst others calcineurin inhibitors. We performed a multicenter randomized trial to study the effects of withdrawal of ciclosporin (CsA) from a triple immunosuppressive regimen at 6 months after transplantation. This study is designed to offer the patients “tailored made” immunosuppressive therapy aiming for a very low incidence of acute rejection and a minimum of side effects, such as cardiovascular damage and nefrotoxicity.

Onderzoeksopzet

Pre-Tx1 Week

“2” Week

4-6 Month

3 Month

6 Month

7 Month

12 Month

18 Month

24 Month.

Onderzoeksproduct en/of interventie

The effects of longtime maintenance therapy with everolimus or with MPS in combination with prednisolone will be evaluated. Both drugs will be given orally. Dosages will be guided by calculating drug exposure, using a validated computer model based on a limited sampling strategy. Reference therapy consists of ciclosporin in combination with prednisolone. Drug exposure of ciclosporin will be monitored closely as well.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients, between the age of 18 en 70 years, receiving a first or second renal transplant;

2. Patients had to understand the purpose and risks of the study;

3. Patients had to give written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with a HLA-identical sibling donor;

2. a third or a fourth transplant;

3. current or historical panel reactive antibodies of more than 50%;

4. female patients unwilling to use adequate contraception during the study;

5. a cholesterol > 8.5 mmol/l despite HMG co-A reductase inhibition.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	270
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-01-2009
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	NL1544
NTR-old	NTR1615
Ander register	: kwkirjjn
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten