Minimization of maintenance immunosuppression early after renal transplantation.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22724

Source
Nationaal Trial Register

Brief title
MECANO

Health condition

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

Sponsors and support

Primary sponsor: Novartis Pharma
Source(s) of monetary or material Support: Novartis Pharma

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Cardiovascular (surrogate) endpoints; IMT Intima/Media Thickness of the a. carotis interna;

2. Blood pressure and the number of antihypertensives;

3. Lipid profile;

4. Renal allograft survival and function (Nankivell), and patient survival;

5. The incidence of malignancies;

6. Infectious complications;

7. Miscellaneous;

fasting glucose, HbA1c, uric acid
MPA-levels and IMPDH activity over time, everolimus levels. MPA and everolimus levels over time (AUCs) will be correlated to graft function, rejection episodes and trough levels.

Study description

Study objective

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.

Study design

Pre-Tx1 Week

“2” Week

4-6 Month

3 Month

6 Month

7 Month

12 Month

18 Month

24 Month.

Intervention

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.

Contacts

Public
Academic Medical Center (AMC), Renal Transplant Unit,
P.O. Box 22660
F. Bemelman
Meibergdreef 9
Amsterdam
The Netherlands
+31 (0)20 5669111
Scientific
Academic Medical Center (AMC), Renal Transplant Unit,
P.O. Box 22660
F. Bemelman
Meibergdreef 9
Amsterdam
The Netherlands
+31 (0)20 5669111

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2005
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-01-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1544
NTR-old	NTR1615
Other	: kwkirjjn
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results