Mycophenolate sodium vs Everolimus or Ciclosporin with Allograft Nephropathy as Outcome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25640

Source
NTR

Brief title
MECANO

Health condition

prospective, open, randomized multicenter

Sponsors and support

Primary sponsor: MECANO Steering group
Chair: S.Surachno/F.Bemelman
Source(s) of monetary or material Support: Novartis Pharma

Intervention

Outcome measures

Primary outcome

Degree of inflammation and fibrosis and degree of arteriolar hyalinosis in renal biopsies taken at 6 and 24 months after implantation.

Secondary outcome

1. Vascular assesments by IMT and M-mode of carotis interna;

2. Bloodpressure and number of antihypertensive drugs;

3. Lipid profile;

4. Renal allograft survival and function;

5. Patient survival;

6. Incidence of malignancies;

7. Infectious complications.

Study description

Background summary

This study compares the results on changes of renal allograft histology by optimal use of ciclosporin, mycophenolate sodium and everolimus (primary endpoints). Furthermore cardiovascular, infectious and oncologic endpoints will be assessed in each group and compared to each other.

Study objective

By achieving optimal immunosuppression with minimal sideeffects due to controled drugexposure by target AUC's we expect reduction of druginduced damage on kidney and cardiovascular system. Three drugs will be subject of study: ciclosporin, mycophenolate and everolimus.

Study design

N/A

Intervention

By achieving stable state 6 months after renal transplantation a baseline renal allograft biopsy is performed and randomisation in one of the three arms of the study takes place.

Arm 1: prednisolon and AUC guided ciclosporin treatment;

Arm 2 : prednisolon and AUC guided mycophenolate mofetil sodium treatment;
Arm 3: prednisolon and AUC guided everolimus treatment. All treatment arm have a duration of 18 month whereafter a final renal allograft biopsy is performed.

It has to be noted that for the 3 treatmentarms no separate control group is defined because no data exists adressing the "golden standard" treatment after renal transplantation.

Contacts

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Eligibility criteria

Inclusion criteria

1. First or second renal transplant;

2. Female or male 18-70 years;

3. Cadaveric or non-HLA identical living donor;

4. Understands risks and purpose of study;

5. written informed consent.

Exclusion criteria

1. Double kidney transplants, kidney-pancreas transplants, 3rd or 4th transplant;

2. PRA > 50% historic or current;

3. Pregnancy or unwilling to use contraception during the study;

4. Cholesterol > 8,5 mmol/l;

5. History of therapy resistance against HMG co-reductase inhibitors.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2004
Enrollment:	255
Type:	Actual

Ethics review

Positive opinion

Date:	17-01-2006
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	NL523
NTR-old	NTR567
Other	: N/A
ISRCTN	ISRCTN69188731

Study results

Summary results
N/A