

Mycophenolate sodium versus Everolimus or Cyclosporine with Allograft Nephropathy as Outcome

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/01/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR567

Study information

Scientific Title

A prospective, open, randomized, multicenter study comparing the effects of everolimus versus mycophenolate sodium as compared to ciclosporin as maintenance therapy in renal allograft recipients, on chronic allograft damage and cardiovascular parameters.

Acronym

MECANO

Study objectives

By achieving optimal immunosuppression with minimal side-effects due to controlled drug exposure by target AUCs, we expect reduction of drug-induced damage on kidney and cardiovascular system. Three drugs will be the subject of the study: cyclosporine, mycophenolate and everolimus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre, randomised, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Renal transplant

Interventions

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

Arm 1: prednisolone and AUC guided cyclosporine treatment

Arm 2 : prednisolone and AUC guided mycophenolate mofetil sodium treatment

Arm 3: prednisolone and AUC guided everolimus

All treatment arms have a duration of 18 months where after a final renal allograft biopsy is performed.

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

mycophenolate sodium, everolimus, cyclosporine

Primary outcome measure

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

Secondary outcome measures

1. Vascular assessments by IMT and M-mode of carotis interna
2. Blood pressure and number of antihypertensive drugs
3. Lipid profile
4. Renal allograft survival and function
5. Patient survival
6. Incidence of malignancies
7. Infectious complications

Overall study start date

01/01/2004

Completion date

01/01/2008

Eligibility**Key inclusion criteria**

1. First or second renal transplant
2. Female or male 18-70 years old
3. Cadaveric or non-HLA identical living donor
4. Understands risks and purpose of study
5. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

255

Key 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

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Center (AMC), Renal Transplant Unit (The Netherlands)

Sponsor details

P.O. Box 22660

Amsterdam

Netherlands

1100 DD

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharma BV (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	retrospective substudy results	01/05/2014		Yes	No