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Mycophenolate sodium versus Everolimus or Cyclosporine with Allograft Nephropathy as Outcome

Submission date 14/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/02/2006	**Overall study status** Completed	
Last Edited 08/01/2015	**Condition category** Surgery	

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