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Safety and efficacy of mycophenolate mofetil in pediatric renal transplantation

Submission date	Recruitment status	[_] Prospectively registered
01/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/01/2008	Urological and Genital Diseases	

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
NTR800

Study information

Scientific Title

Study objectives
1. Mycophenolate Mofetil (MMF)/prednisolone is as efficacious in prevention of acute rejections as Cyclosporin A (CsA)/prednisolone
2. MMF/prednisolone is safer than CsA/prednisolone, in renal function, lipids, and blood pressure

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, multicentre parallel armed, controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Nor ptovided at time of registration

Health condition(s) or problem(s) studied
Renal transplant

Interventions
Start trial is one year after transplantation. Randomisation between two groups: continuing with MMF/prednisolone or CsA/prednisolone by withdrawal over three months of the third immunosuppressive drug.

During the three months of withdrawal, the prednisolone dosage is doubled. Follow-up is two years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mycophenolate mofetil (MMF), prednisolone and cyclosporin A (CsA)

Primary outcome measure
1. Glomerular filtration rate
2. Incidence of acute rejections
3. Serum lipids
4. Blood pressure and number of antihypertensive drugs

Secondary outcome measures
1. Graft survival
2. Incidence of malignancies
3. Incidence of viral infections
4. Incidence of anemia

Overall study start date
01/01/2000

Completion date
01/12/2005

Eligibility

Key inclusion criteria
1. All Dutch children, receiving a first kidney transplant after 01/01/2000
2. Treated with initial immunosuppression corticosteroids, MMF and CsA, during the latter part of the study with addition of basiliximab

Participant type(s)
Patient

Age group
Child

Sex
Not Specified

Target number of participants
44

Key exclusion criteria
1. Not on triple therapy (prednisolone/CsA/MMF) at the end of the first year
2. More than one acute rejection episode
3. Rejection episode being not steroid sensitive
4. No written informed consent

Date of first enrolment
01/01/2000

Date of final enrolment

01/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GJ

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

Sponsor details
Sophia Children's Hospital
Dr Molewaterplein 60
Rotterdam
Netherlands
3015 GJ

Sponsor type
Hospital/treatment centre

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Charity

Funder Name
Dutch Kidney Foundation (Nierstichting Nederland) (The Netherlands)

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
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	Results	27/04/2007		Yes	No