Safety and efficacy of mycophenolate mofetil in pediatric renal transplantation

Submission date	Recruitment status No longer recruiting	Prospectively registered		
01/12/2006		Protocol		
Registration date 01/12/2006	Overall study status Completed	Statistical analysis plan		
		[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

Contact name

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Contact details

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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

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