

# Safety and efficacy of mycophenolate mofetil in pediatric renal transplantation

<b>Submission date</b> 01/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/01/2008	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Karlien Cransberg

**Contact details**  
Erasmus Medical Center  
Sophia Children's Hospital  
Dr Molewaterplein 60  
Rotterdam  
Netherlands  
3015 GJ  
+31 (0)10 4636363  
k.cransberg@erasmusmc.nl

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

Not Specified

**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)

## 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

## 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?
<a href="#">Results article</a>	Results	27/04/2007		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes