

Mycophenolate in children with an idiopathic nephrotic syndrome.

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/07/2009	Condition category 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 E.M. Dorresteijn

Contact details
Rijnland Hospital
Department of Pediatrics
P.O. Box 4220
Leiderdorp
Netherlands
2350 CC

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR502

Study information

Scientific Title

Randomised multi-centre study comparing mycophenolate and cyclosporin A in children with a frequent relapsing or corticoid dependent idiopathic nephrotic syndrome

Study objectives

Mycophenolate mofetil is effective in preventing relapses of nephrotic syndrome and has less nephrotoxic effects compared to cyclosporin A.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Nephrotic syndrome

Interventions

Randomisation for mycophenolate or cyclosporin A.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Mycophenolate mofetil, cyclosporin A

Primary outcome measure

GFR

Secondary outcome measures

1. Relapse rate
2. Other adverse effects

Overall study start date

01/12/2002

Completion date

01/06/2005

Eligibility

Key inclusion criteria

1. Children <18 years
2. Minimal change nephrotic syndrome
3. Glomerular filtration rate (GFR) >80 ml/1.73 m²/min
4. Steroid dependency or frequent relapsing

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

31

Key exclusion criteria

1. Severe anemia or leucopenia
2. Active infection
3. Failure of cyclosporin treatment in history

Date of first enrolment

01/12/2002

Date of final enrolment

01/06/2005

Locations

Countries of recruitment

Netherlands

Study participating centre
Rijnland Hospital
Leiderdorp
Netherlands
2350 CC

Sponsor information

Organisation
Rijnland Hospital (Netherlands)

Sponsor details
P.O. Box 4220
Leiderdorp
Netherlands
2350 CC

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/05vc4qy60>

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV (Netherlands)

Funder Name
Erasmus Medical Center (Netherlands)

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

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	01/11/2008		Yes	No