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Mycophenolate in children with an idiopatic nephrotic syndrome.

Submission date	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2009	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
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