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Therapy of frequent relapsing, steroid-sensitive nephrotic syndrome in childhood: efficacy of mycophenolate mofetil versus cyclosporin A

Submission date	Recruitment status	[_] Prospectively registered
24/03/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/05/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/09/2007	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.apn-online.de/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ML 16622

Study information

Scientific Title

Study objectives
Immunosuppressive therapy with mycophenolate mofetil (MMF) is as effective as cyclosporin A in preventing relapses of the nephrotic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of Charité - University Medicine Berlin (Germany) on the 2nd December 2002 (ref: 1656/Si 238).

Study design
Multicentre, randomised, open-labelled, cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Idiopathic nephrotic syndrome

Interventions
Immunosuppressive therapy with MMF versus cyclosporin A.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mycophenolate mofetil, cyclosporin A

Primary outcome measure

Number of relapses during the observation period

Secondary outcome measures
Decrease in GFR, hypertension and hyperlipidemia during the observation period

Overall study start date
01/01/2004

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Children aged 3 - 17 years
2. Frequent relapses of steroid-sensitive nephrotic syndrome, associated with minimal changes on renal biopsy
3. Glomerular Filtration Rate (GFR) greater than 70 ml/min

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
55

Key exclusion criteria
1. Other histological findings on renal biopsy
2. Other severe concomittant diseases
3. Decreased GFR

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Germany

Study participating centre
Augustenburger Platz 1
Berlin
Germany
13353

Sponsor information

Organisation
Hoffmann-La Roche AG (Germany)

Sponsor details
Emil-Barell-Strasse 1
Grenzach-Wyhlen
Germany
79639

Sponsor type
Industry

Website
http://www.roche.de

ROR
https://ror.org/00sh68184

Funder(s)

Funder type
Industry

Funder Name
Hoffmann La Roche AG (Germany)

Funder Name
Charité - University Medicine Berlin (Germany)

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	01/01/2004		Yes	No