

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

Submission date

24/03/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

26/05/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

20/09/2007

Condition category

Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.apn-online.de/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

Augustenburger Platz 1

Berlin

Germany

13353

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