ISRCTN06912061 https://doi.org/10.1186/ISRCTN06912061

Prospective, multicenter, double-blind, randomized, cross-over study to evaluate efficacy and safety of sevelamer in the treatment of dyslipidemia in children with persisting proteinuria

Submission date	Recruitment status	[ ] Prospectively registered
23/03/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/05/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/05/2006	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
EK 1656/Si 238

Study information

Scientific Title

Study objectives
Sevelamer, but not placebo, lowers hypercholesterolemia in children with persisting proteinuria or nephrotic syndrome

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin on 05/09/2002, reference number 1778 /Si 254

Study design
Randomized controlled, cross-over, double-blind, multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Glomerular diseases with proteinuria

Interventions
Sevelamer versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sevelamer

Primary outcome measure
Decrease in serum cholesterol

Secondary outcome measures
1. Decrease in other lipids
2. Markers of oxidative stress
3. Proteinuria

Overall study start date
01/01/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Children aged 2-18 years, with persisting proteinuria and hypercholesterolemia.

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Chronic renal insufficiency (glomerular filtration rate [GFR] <40 ml/min)
2. Genetic forms of hyperlipidemia
3. Hyperlipidemia due to other causes

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Germany

Study participating centre
Charité - University Medicine Berlin
Berlin
Germany
13353

Sponsor information

Organisation
Genzyme Europe

Sponsor details
310 Cambridge Science Park
Cambridge
United Kingdom
CB4 OWG

Sponsor type
Industry

ROR
https://ror.org/02n6c9837

Funder(s)

Funder type
Industry

Funder Name
Genzyme Europe

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