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

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
Decrease in serum cholesterol

Key secondary outcome(s)
1. Decrease in other lipids
2. Markers of oxidative stress
3. Proteinuria

Completion date
31/12/2007

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
All

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

ROR
https://ror.org/02n6c9837

Funder(s)

Funder type
Industry

Funder Name
Genzyme Europe

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration