

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 23/03/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 26/05/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/05/2006	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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