Efficacy and safety of ezetimibe in young children with familial hypercholesterolemia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25426

Source
NTR

Brief title
EZKIMO

Health condition

Familial hypercholesterolemia

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC), Department of Vascular Medicine

Source(s) of monetary or material Support: medication will be supplied by:
Merck Sharp and Dohme and
Schering Plough

Intervention

Outcome measures

Primary outcome

Primary endpoint will be the efficacy towards LDL-C levels and the safety of 10 mg ezetimibe.

Secondary outcome

Secondary endpoint will be the effect of 10 mg ezetimibe on inflammatory markers and plant sterols in plasma.

Study description

Background summary

In 70 young children with FH we will examine the safety of ezetimibe 10mg monotherapy and the efficacy on plasma lipid levels, plantsterols and inflammatory markers.

Study objective

Ezetimibe monotherapie lowers LDL-C levels, plant sterol levels and inflammatory markers in young children with familial hypercholesterolemia.

Study design

N/A

Intervention

Ezetimibe 10 mg/day or placebo treatment during 4 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Males or females;

2. Aged 8-14 years;

3. Heterozygous Familial hypercholesterolemia defined as:

a. Molecular diagnosis of FH AND LDL-cholesterol above 95th percentile for age and sex (LDL-C> 3.88 mmol/L) despite a lipid-lowering diet for at least 3 months; OR

b. LDL-cholesterol above 95th percentile for age and sex (LDL-C> 3.88 mmol/L) despite a lipid-lowering diet for at least 3 months; AND

c. One parent with either a clinical or molecular diagnosis of FH.

Exclusion criteria

1. Homozygous familial hypercholesterolemia;

2. Diseases that cause a secondary increase in LDL-C, such as diabetes mellitus, anorexia nervosa and renal, hepatic or thyroid disease;

3. Length below the 3rd percentile for age and sex;

4. Weight-compared-to-length above the 97th percentile for age and sex;

5. Serious illness in the previous three months;

6. Major surgery in the previous three months;

7. Partial ileal bypass or any gastrointestinal disease that might interfere with drug absorption;

8. Plasma triglycerides above 4.0 mmol/l;

9. Hypertension (systolic > 160 mm Hg or diastolic > 100 mm Hg);

10. Psychological disorders that might interfere with adherence to the protocol;

11. Pregnancy at baseline;

12. History of allergy or sensitivity to ezetimibe;

13. Liver function tests, ASAT or ALAT, must be < 1.5 times the upper limit of normal (ULN) using the central laboratory reference range;

14. CK levels must be <1.5 times the ULN using the central laboratory reference range.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2006
Enrollment:	70
Type:	Actual

Ethics review

Positive opinion

Date:	04-04-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL594
NTR-old	NTR650
Other	: N/A
ISRCTN	ISRCTN39762831

Study results

Summary results
N/A