

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25426

Bron

NTR

Verkorte titel

EZKIMO

Aandoening

Familial hypercholesterolemia

Ondersteuning

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

Overige ondersteuning: medication will be supplied by:

Merck Sharp and Dohme and
Schering Plough

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2006
Aantal proefpersonen:	70
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 04-04-2006

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A