Ten years of statin therapy started in childhood: efficacy, safety, compliance and tolerability in patients with familial hypercholesterolemia (AfterTen-study)

Published: 12-12-2008
Last updated: 06-05-2024

This study will evaluate the effect of approximately 10 years of pravastatin treatment on IMT in young adults with FH. Furthermore, safety parameters and psychological aspects with respect to early treatment initiation will be investigated.

Ethical review	Approved WMO
Status	Pending
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON32864

Source
ToetsingOnline

Brief title
AfterTen

Condition

- Metabolic and nutritional disorders congenital
- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
familial elevated cholesterol, familial hypercholesterolemia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Familial hypercholesterolemia, Intima Media Thickness (IMT), Statin

Outcome measures

Primary outcome

The main endpoint will be the difference in IMT between FH patients and their non-affected siblings after 10 years follow-up.

Secondary outcome

Furthermore, we will investigate change in IMT after 10 years follow-up for various treatment durations and intensities. The occurrence of adverse events and growth and sexual development will be described and compared to healthy siblings. We will also investigate psychological effects.

Study description

Background summary

In the LIPIDS trial, children aged 10-18 with Familial hypercholesterolemia (FH), an hereditary disorder characterized by elevated levels of low-density lipoprotein cholesterol (LDL-C) causing premature atherosclerotic cardiovascular events, have been treated with pravastatin 20-40 mg. This agent was safe and effective in lowering LDL-C and intima media thickness (IMT) progression, a surrogate marker for atherosclerosis, during the study. However the effect of such early treatment initiation, mainly with respect to atherosclerosis progression in the long term, is not exactly known.

Study objective

This study will evaluate the effect of approximately 10 years of pravastatin treatment on IMT in young adults with FH. Furthermore, safety parameters and

psychological aspects with respect to early treatment initiation will be investigated.

Study design

Patients who participated in the LIPIDS trial (n=204) as well as their non-affected siblings (n*80), will be requested to visit our center once. During the visit we will obtain medical history, perform a physical examination, measure IMT and draw blood. Furthermore, a questionnaire on medication use and psychological aspects will be filled out. FH patients will be asked for permission to contact their physicians who treat them with respect to FH in order to verify data on medication use and medical history.

Study burden and risks

Patients will pay only one visit of approximately 3 hours for blood sampling (50 ml), medical history and physical examination, filling out a questionnaire with respect to psychological aspects and IMT measurement. We consider this of minimal burden for the participants. Patients who are not treated according to current best practice will benefit from participation since their treatment regimens will be optimized according to current guidelines.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Those who participated in the LIPIDS trial and their non-affected brothers or sisters

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	294
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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
CCMO	NL24994.018.08