Familial Hypercholesterolemia: Assessment of Cardiovascular Risk by Measuring Intima-Media and Achilles Tendon Thickness in Persons with Diverse Cholesterol Profiles - FLAMINCHO

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To test the hypothesis whether the Intima Media Thickness differs between FH carriers without apparent dyslipidemia and the group of FH carriers with apparent dyslipidemia and a control group consisting of persons tested by the StOEH who did not…

Ethical review	Approved WMO
Status	Pending
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON31368

Source
ToetsingOnline

Brief title
FLAMINCHO

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Familial Hypercholesterolemia, Hereditary high cholesterol

Research involving
Human

Sponsors and support

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

Intervention

Keyword: (carotid) Intima-Media Thickness, Genetic cascade screening, Hyperlipoproteinaemia Type II, LDL-cholesterol

Outcome measures

Primary outcome

(carotid) Intima media thickness compared between groups

Secondary outcome

Achilles tendon thickness compared between groups

General (Total cholesterol, HDL cholesterol, LDL cholesterol etc.)

Study description

Background summary

FH carriers have a severely increased risk of development of arterial vascular problems, in particular of coronary heart disease. When left untreated FH carriers suffer from cardiovascular disease on average at 45 years and women on average 10 years later. Early detection and start of cholesterol lowering medication early in life can result in substantial increase in life expectancy. For that reason a genetic cascade screening for detecting of FH has been performed in the Netherlands since 1994. The mode is genetic cascade screening, meaning that if in an index patient a mutation has been detected the first generation family members of this individual will be tested for the presence of that specific mutation and if present so onwards. Recent data suggests that in the last few years increasing percentage of FH carriers detected have no or only mild dyslipidemia. The prognosis with respect to cardiovascular risk of this group is unknown. We hypothesise that the Intima Media Thickness used as estimate of cardiovascular risk in the group of FH carriers without apparent dyslipidemia differs significantly from the group of FH carriers with apparent dyslipidemia.

Study objective

To test the hypothesis whether the Intima Media Thickness differs between FH carriers without apparent dyslipidemia and the group of FH carriers with apparent dyslipidemia and a control group consisting of persons tested by the StOEH who did not have FH. Subsequently an objective is to test whether Achilles Tendon Thickness assessed by ultrasound could aid the clinical diagnosis of FH in the group of FH-carriers with a relatively low LDL-cholesterol.

Study design

This study consists of an observational study with a single study visit. During this visit a medical history, examination, blood collection and an ultrasound measurement of the carotid intima-media thickness and achilles tendon thickness will be performed.

Study burden and risks

Hardly any risks are involved in this study. A single venapuncture, during which 50 ml blood will be collected, will be done. Furthermore a non invasive ultasound of the carotid arteries and the Achilles tendons will be performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Included are persons aged 18-50 years with a molecular diagnosis of Familial Hypercholesterolemia with an LDL-cholesterol either below or above their age- and sex-specific 75th or 90th percentile respectively on their fasting treatment naïve lipid measurement performed by the StOEH (Foundation for Identification of Hereditary Hypercholesterolemia) during first visit. The inclusion criteria for the healthy control population are described in a separate MEC application.

Exclusion criteria

Excluded are persons in whom for example due to surgery in the cervical region carotid Intima-Media Thickness measurements will be technically not possible to perform; and persons who were screened by the StOEH more than 18 months before we can approach them, persons with a body mass index over 35 kg/m2;. Furthermore, patients with a serious uncontrolled hepatic, haematological, renal, gastrointestinal, endocrinological, pulmonary, cardiac or neurological disorder will be excluded; and persons who have noted that they don*t want to be approached for further research.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	300
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	NL17965.018.07