GENETIC CAUSES OF DYSLIPIDEMIA AND CARDIOVASCULAR DISEASE

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We set out to evaluate the genetic basis of dyslipidemia and cardiovascular disease.

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON32094

Source
ToetsingOnline

Brief title
GENEVA

Condition

- Coronary artery disorders
- Cardiac and vascular disorders congenital
- Lipid metabolism disorders

Synonym
dyslipidemia, lipid disorder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cardiovascular disease, dyslipidemia, genetics

Outcome measures

Primary outcome

Primary endpoints:

- Determination of the atherosclerotic burden by means of cIMT and FMD of rare genetically determined dyslipidemia and/or cardiovascular disease

- Identification of genetic causes of unexplained dyslipidemia and/or cardiovascular disease

Secondary outcome

NA

Study description

Background summary

Hereditary disorders of lipid metabolism are rare. Therefore it is not entirely known what these disorders teach us about normal function of lipid metabolism. Furthermore, in many of these disorders, the effect on atherosclerotic risk is undetermined. Clarification of this effect would elucidate the importance of the genes and proteins in lipid metabolism.
Some patients develop cardiovascular disease that cannot be sufficiently explained by underlying risk factors. Sometimes entire families are affected. An unidentified genetic defect/disorder could explain this pattern.

Study objective

We set out to evaluate the genetic basis of dyslipidemia and cardiovascular disease.

Study design

This study will focus on index patients and their families with genetically defined dyslipidemia and/or cardiovascular disease. If specific dyslipidemic or

cardiovascular disorders are identified, we plan to perform cross-sectional case-control studies. The results obtained in genetically affected subjects are compared with family controls that are matched for age, sex and smoking status. All patient data and samples will be stored for 15 years.

Study burden and risks

The study consists of a house visit with blood withdrawal, and a visit to the hospital, where ultrasonograpic imiaging will take place. We will determine thickness of the vascular wall of the carotid artery in the neck: intima media thickness (IMT). We will also measure flow mediated dilation (FMD) of of the artery in the lower arm. This reflects function of the endothelium, the tissue that covers the inside of vessel wall. In some cases, a small skin biopsy will be performed.

bepaling van de dikte van de vaatwand van de halsslagader: intima media thickness (IMT). Ook willen we flow mediated dilation (FMD) van de onderarmsslagader meten, een maat voor de functie van het endotheel, de vaatwandbekleding.
In enkele gevallen zal ook een huidbiopsie verricht worden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

dyslipidemia, cardiovascular disease, positive family history for cardiovascular disease

Exclusion criteria

Secundary dyslipidemia

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2008
Enrollment:	10000
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	NL22040.018.08