

Study To Investigate Carotid atherosclerosis in carriers of LCAT gene mutations and unaffected family controls: A 3.0 Tesla Magnetic Resonance Imaging study

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We therefore set out to study the relationship of LCAT with atherosclerosis using 3.0 Tesla MRI mean wall area (MWA) measurements of the carotid arteries as a marker for atherosclerosis in a cohort of LCAT mutation carriers and compare them to...

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

Summary

ID

NL-OMON32476

Source

ToetsingOnline

Brief title

STIC-LCAT

Condition

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

Synonym

atherosclerosis, cardiovascular disease

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 atherosclerosis, LCAT, MRI

Outcome measures

Primary outcome

mean wall area of carotid arteries as assessed by MRI

Secondary outcome

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Study description

Background summary

LCAT plays a key role in the maturation of HDL particles. Norum and Gjone first described that LCAT gene mutations underlie familial LCAT deficiency. Familial LCAT deficiency is characterized by HDL deficiency (5% to 10% of normal HDLc levels).

Although LCAT has thus long been known to play an important role in HDL metabolism, its association with atherosclerosis remains elusive. Two previous studies in carriers of LCAT gene mutations using ultrasound intima-media thickness (IMT) measurements have provided contradictory results. A study by Hovingh et al. found a significantly increased ultrasound IMT in carriers of LCAT gene mutations as compared to unaffected family controls, while Calabresi et al. did not find a difference in IMT in a comparable case control study (data presented on Sessions of the International Atherosclerosis Society, Santorini Greece 2007). Because of the rarity of LCAT gene mutations and the limited number of carriers of LCAT gene defects, the population sizes that can be studied and compared are small. Although ultrasound IMT measurements are a useful tool for large population based studies, the power to detect differences in smaller patient groups is poor. This might be an explanation for these contradictory findings. The relation between LCAT gene mutations and atherosclerosis therefore remains largely unclear. Recent advances in carotid artery MRI enable the detection of differences in

artery wall dimensions in small populations with greater power.

Study objective

We therefore set out to study the relationship of LCAT with atherosclerosis using 3.0 Tesla MRI mean wall area (MWA) measurements of the carotid arteries as a marker for atherosclerosis in a cohort of LCAT mutation carriers and compare them to unaffected family controls.

Study design

Cross sectional matched case-control study

Study burden and risks

Study takes 3 hours per participant. No risks involved.

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

Subjects who are carriers of LCAT gene mutations, aged between 18 and 75 years of age, and healthy unaffected family controls, aged between 18 and 75 years, matched for age, gender, body mass index (BMI, in kg/m²) and smoking.

Exclusion criteria

Metal in the body, as a result of e.g. osteosynthetic material, pacemaker or artificial cardiac valves; claustrophobia; surgery performed in the area of measurement (Carotid artery region); cardiac arrhythmias.

Study design

Design

Study type:	Observational non 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):	01-09-2008
Enrollment:	80
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	NL24399.018.08