Improved Assessment of Cardiovascular Risk Through Imaging in Relatives Identified By Lipoprotein(a) Cascade Screening

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The objective is to assess whether individuals identified with elevated Lp(a) through familial cascade screening have an increased presence of coronary atherosclerotic plaque compared to matched controls with normal Lp(a).

Ethical review	Approved WMO
Status	Pending
Health condition type	Lipid metabolism disorders
Study type	Observational invasive

Summary

ID

NL-OMON57393

Source
ToetsingOnline

Brief title
IMAGE-LPA

Condition

- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, heart and blood vessel disease

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular disease, Cardiovascular risk, CCTA, Lipoprotein(a)

Outcome measures

Primary outcome

The main study parameter is the presence of coronary plaque measured via CCTA.

Secondary outcome

Secondary parameters include the presence of obstructive stenosis, total

coronary plaque volumes, calcified and non-calcified plaque volumes,

low-attenuation plaque, pericoronary adipose tissue attenuation, high risk

plaque features, and the CAD-RADS classification.

Study description

Background summary

This study aims to address the current knowledge gap regarding the relationship between elevated Lipoprotein(a) (Lp(a)) and subclinical atherosclerosis in patients that have been identi-fied through familial Lp(a) cascade screening. Despite Lp(a) being a known genetic risk factor for ASCVD, the clinical significance of detecting elevated Lp(a) through familial cascade screening, particularly among individuals in primary prevention, is unclear.

Study objective

The objective is to assess whether individuals identified with elevated Lp(a) through familial cascade screening have an increased presence of coronary atherosclerotic plaque compared to matched controls with normal Lp(a).

Study design

This is an observational cohort study comparing two groups: individuals identified through familial cascade screening with elevated Lp(a) and matched controls with normal Lp(a) levels. The study will use CCTA and CAC scoring to assess subclinical atherosclerosis in both groups.

Study burden and risks

Participants will undergo medical history taking, physical examination, blood sampling, and CCTA imaging, which involves exposure to a small amount of radiation and the use of contrast agents. These procedures are associated with minimal discomfort. The benefits include early detection of subclinical atherosclerosis, enabling timely preventive measures as proposed by the current CVRM guidelines. The use of contrast media poses a low risk of nephrotoxicity, mitigated by excluding participants with renal insufficiency. Participants may also experience anxiety from potential incidental findings, but stand to gain more insight into their cardiovascular risk profile.

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

In order to be eligible to participate in this study in the elevated Lp(a) subgroup, a subject must meet all of the following criteria:
• Man or woman >=50 years of age;
• Lp(a) level >= 150 nmol/L;
• Identified as having elevated Lp(a) through Lp(a) family cascade screening at the Amsterdam UMC Vascular Medicine outpatient clinic;
• Able and willing to provide informed consent;
• Able to comply with study requirements.

In order to be eligible to participate in this study in the control subgroup, a subject must meet all of the following criteria:
• Man or woman >=50 years of age;
• Lp(a) level < 50 nmol/L;
• Participated in Lp(a) family cascade screening at the Amsterdam UMC Vascular Medicine outpatient clinic as family member of index patient;
• Able and willing to provide informed consent;
• Able to comply with study requirements.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study (both subgroups):
• Renal insufficiency, defined as eGFR < 30 ml/min
• History of ASCVD (acute coronary syndrome, history of myocardial infarction, stable or unstable angina pectoris or coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral artery disease including aortic aneurysm, all of atherosclerotic origin)
• History of atrial fibrillation
• Prior and current use of statins
• Any other treatment or clinically relevant condition that could interfere with the conduct or interpretation of the study in the opinion of the investigator
• Unable or unwilling to provide informed consent
• Unable to comply with study requirements.

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):	01-03-2025
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-03-2025
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	NL88112.018.24