T-cell activation in high lipoprotein(a) patients

Published: 01-07-2020
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To assess T cell activation in patients with extremely high Lp(a) levels versus controls with low Lp(a)

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

Summary

ID

NL-OMON49849

Source
ToetsingOnline

Brief title
T-cell activation in high lipoprotein(a) patients

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis, cardiovascular disease, high lipoprotein(a)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiovascular disease, Lipoproteïn(a), T-cell activation

Outcome measures

Primary outcome

We will compare the phenotype, cytokine production and epigenetic characteristics of T cells between patients with high and low Lp(a), with and without a history of cardiovascular disease. Additionally, we will determine the conditions under which healthy T cells are promoted to pro-inflammatory phenotypes and evaluate the ex vivo reversibility of this phenotype.

Secondary outcome

NA

Study description

Background summary

Patients with high lipoprotein(a) (Lp[a]) levels are characterised by accelerated atherosclerosis. However, the mechanisms underlying this increased risk remain largely unknown. Recent data indicates that T cells form the principal cell population in atherosclerotic plaque. As the atherosclerotic burden associated with high Lp(a) is thought to derive more from inflammatory signalling than from the sole accumulation of lipids, we hypothesise this patient group in particular will be characterised by profound T cell activation compared to controls with normal Lp(a) levels, both in subjects with and without a history of cardiovascular disease (CVD).

Study objective

To assess T cell activation in patients with extremely high Lp(a) levels versus controls with low Lp(a)

Study design

Observational case control study

Study burden and risks

Participants will fill out a questionnaire and blood will be withdrawn. Volunteers from the high Lp(a) group could benefit from better insight into the pathophysiological mechanisms mediating accelerated atherosclerosis, which could lead to the development of novel therapies. Participants from the low Lp(a) group have no benefit of participating in the study.

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

1. High lipoprotein(a) with known cardiovascular disease
2. Low lipoprotein(a) with known cardiovascular disease

3. High lipoprotein(a) without known cardiovascular disease
4. Low lipoprotein(a) without known cardiovascular disease

Exclusion criteria

- HIV
- Chronic kidney disease
- Any condition which could possibly interfere with the conduction or outcome of the study to the opinion of the investigator

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2020
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	NL73695.018.20