A Multicenter, Cross-sectional Study to Characterize the Distribution of Lipoprotein(a) Levels Among Patients With Documented History of Atherosclerotic Cardiovascular Disease (ASCVD)

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Primary:-To identify subjects with documented history of myocardial infarction (MI) and/or percutaneous coronary intervention (PCI) and lipoprotein(a) (Lp[a]) levels >=90 mg/dL or Lp(a) >=200 nmol/LSecondary:-Evaluate the distribution of Lp(a...

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

Summary

ID

NL-OMON53411

Source
ToetsingOnline

Brief title
20210057

Condition

- Lipid metabolism disorders

Synonym
Atherosclerosis, Coronary heart disease

Research involving

Human

Sponsors and support

Primary sponsor: Amgen
Source(s) of monetary or material Support: Amgen

Intervention

Keyword: cardiovascular, Lp(a)

Outcome measures

Primary outcome

-Lp(a) value.

-Lp(a) value >= 90 mg/dL or >=200 nmol/L for the subgroup of subjects with known

Lp(a) value.

Secondary outcome

-Lp(a) value.

Study description

Background summary

Cardiovascular disease remains the leading cause of death and disability worldwide according to the World Health Organization. While lipid-lowering therapy research has historically focused on low density lipoprotein cholesterol to reduce Cardiovascular risk, evidence identifies elevated plasma Lp(a) as a strong independent risk factor for ASCVD. Lp(a) has been shown to be a risk factor for cardiovascular disease. High plasma Lp(a) concentration is predominantly genetically defined, remains at stable levels, cannot be readily controlled by habit modifications (diet, exercise, or other environmental factors), and is not effectively controlled by any of the currently available lipid reducing medications. Currently, there are no approved therapies to lower Lp(a).

Study objective

Primary:

-To identify subjects with documented history of myocardial infarction (MI) and/or percutaneous coronary intervention (PCI) and lipoprotein(a) (Lp[a]) levels >=90 mg/dL or Lp(a) >=200 nmol/L

Secondary:
-Evaluate the distribution of Lp(a) value in the overall subjects with documented history of MI and/or PCI.
-Evaluate the distribution of Lp(a) value in subjects with documented history of MI and/or PCI by demographics and regions

Study design

This is a multicenter, cross-sectional study to summarize the Lp(a) distribution in subjects with documented history of MI and/or PCI as defined by their medical history. Subjects will be eligible for the study if their Lp(a) value is unknown or is known to be >= 90 mg/dL, or >= 200 nmol/L. For the subset of subjects with known Lp(a), historical values will be used. In cases where Lp(a) data are not available, blood sampling will be performed to analyze Lp(a) through local laboratories. Medical history and laboratory values for Lp(a), if applicable, will be collected retrospectively. One study visit is needed for data collection and a blood draw to determine Lp(a), if required.

Study burden and risks

No therapy/investigational product will be administered during the course of this study.
The patient will provide written consent in an Informed Consent Form.
For patients with a known Lp(a) value, historical values will be collected for the study from their medical records, no further procedures or requirements will be taken from the patient after consent.
For patients with an unknown Lp(a) value, the patient will be asked to provide a blood sample for laboratory analysis. Once the sample has been analyzed by the laboratory and reported, the study site will contact the patient via telephone or other means (such as electronic communication or in-person contact) and inform them of their Lp(a) value. No further procedures of requirements will be taken from the patient once the follow up visit has been conducted.

Contacts

Public
Amgen

Minervum 7061

Breda 4817 ZK
NL
Scientific
Amgen

Minervum 7061
Breda 4817 ZK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

101. Subject has provided informed consent prior to initiation of any study specific activities/procedures.
102. Age 18 to 85 years.
103. History of ASCVD as demonstrated by either:
a) MI (presumed type 1)
And/or
b) PCI (with high-risk features) with at least 1 of the following:
- Age > 65 years
-Diabetes mellitus
- History of ischemic stroke
- History of peripheral arterial disease
- Residual stenosis >= 50%
- Multivessel PCI (ie, >= 2 vessels, including branch arteries)

See section 5.1 of the protocol.

Exclusion criteria

201. Subjects known to be currently receiving investigational drug in a clinical study that is anticipated to last > 1 year
202. Known Lp(a) value < 90 mg/dL (if measured in mass) or < 200 nmol/L (if

measured in molar).
203. Subject has a diagnosis of end-stage renal disease or requires dialysis
204. Poorly controlled (glycated hemoglobin [HbA1c] > 10%) diabetes mellitus (type 1 or type 2).
205. Subject is receiving or has received lipoprotein apheresis to reduce Lp(a) within 3 months prior to enrollment.
206. Known uncontrolled or recurrent ventricular tachycardia in the past 3 months prior to enrollment.
207. Known malignancy (except non-melanoma skin cancers, cervical in situ carcinoma, breast ductal carcinoma in situ, or stage 1 prostate carcinoma) within the last 5 years prior to enrollment.
208. Known history or evidence of clinically significant disease (eg, respiratory, gastrointestinal, or psychiatric disease) or unstable disorder or biomarker that, in the opinion of the investigator(s), would result in life expectancy < 5 years.
209. Known hemorrhagic stroke.

See section 5.2 of the protocol.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2022
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	22-08-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-04-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL80396.028.22

Study results

Date completed:	28-04-2023

Actual enrolment:	1500