Establishing elevated lipoprotein(a) as a target in calcific aortic valve disease

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Evaluate whether patients with elevated Lp(a) are characterized by increased active calcification of the aortic valve.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON50522

Source
ToetsingOnline

Brief title
CALCIFY

Condition

- Cardiac valve disorders

Synonym
aortic stenosis, heart valve 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: 18F-NaF, calcific aortic valve disase, lipoprotein(a), PET/CT

Outcome measures

Primary outcome

The main study parameter is the difference between groups in 18F-NaF uptake in

the aortic valve, expressed as tissue-to-background ratio.

Secondary outcome

- To evaluate the in vitro calcification capacity of plasma Lp(a) from

participants

Study description

Background summary

Calcific aortic valve disease has a high unmet clinical need. Recent studies demonstrate that elevated lipoprotein(a) (Lp(a)) is highly likely to be causally related to aortic valve stenosis. 18F-NaF PET/CT imaging in patients with aortic stenosis allows for non-invasive detection of active microcalcification.

Study objective

Evaluate whether patients with elevated Lp(a) are characterized by increased active calcification of the aortic valve.

Study design

Single center, cross-sectional study.

Study burden and risks

The results of this study contribute to the recognition of treatable risk factors and development of imaging approaches to ultimately reduce morbidity and mortality in aortic valve stenosis. Considering there are currently no medical therapies to slow progression of aortic valve stenosis, there is a clear medical need to recognize treatable risk factors and establish diagnostic modalities which directly assess disease activity. With the advent of Lp(a)-lowering therapies, we envision 18F-NaF imaging as a method to select patients at risk and monitor therapeutic effects.

In the present study, participating subjects receive no direct or immediate benefits. The burden and risk of participating in this study is estimated to be low. Patients will visit the clinical trial unit at least once for PET/CT imaging procedures (90 minutes). Depending on whether prior Lp(a) levels and echocardiograms are available another screening visit may be needed (60 min). There are no direct adverse effects associated with PET/CT scanning. The maximum exposure related to PET/CT scanning is 9.9 mSv in this study. However, patients included in this study have aortic valve stenosis and while progression rates may vary between patients, progression to severe stenosis and/or symptomatic stenosis is associated with a low event-free survival rate. The potential benefits of establishing novel treatable risk factors for aortic valve stenosis is expected to compensate for the radiation risk. In addition, this study is relevant for a much larger group of aortic valve stenosis patients, who will not have to be exposed to these risks due to this 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult patients, aged 45-80 years old
- Mild to moderate aortic valve stenosis: on echocardiography, aortic valve maximum velocity is >2.0 m/sec

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Severe aortic valve stenosis
- History of radiotherapy of the thorax
- History of rheumatic fever
- Renal insufficiency, defined as eGFR < 30 ml/min
- Hyperparathyroidism
- Paget*s disease of the bone
- Any other treatment or clininically relevant condition that could interfere with the conduct or interpretation of the study in the opinion of the investigator
- Standard contra-indications to PET/CT

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):	09-02-2018
Enrollment:	72

Type:	Actual

Ethics review

Approved WMO Date:	07-12-2017
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	NL62677.018.17