Biological variation of cardiac biomarkers in aortic valve stenosis

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To study the biological variation of cardiac biomarkers (e.g. cardiac troponin T and I, NT-pro-BNP, ST-2, Galectin-3) in clinically stable moderate aortic valve stenosis.

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

Summary

ID

NL-OMON44121

Source
ToetsingOnline

Brief title
Biological variation of cardiac biomarkers in aortic valve stenosis

Condition

- Cardiac valve disorders

Synonym
Aortic stenosis;calcification of the aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aortic valve stenosis, Biological variation, Cardiac biomarkers

Outcome measures

Primary outcome

Concentrations of cardiac biomarkers (eg troponins, NT-pro-BNP, ST-2 and

galectin-3) measured 7 times within 1 year.

Secondary outcome

Not applicable.

Study description

Background summary

Calcified aortic valve stenosis (CAVS) is a progressive disease and nowadays, the cornerstone in diagnostics and follow-up is echocardiography. Cardiac biomarkers (such as cardiac troponins T and I and NT-pro-BNP) hold promise to fulfil a role in early recognition of complications concerning the aortic valve and decompensation. For this purpose, it is important to assess the normal biological variation (BV) of cardiac biomarkers patients with CAVS. This will contribute to a better understanding of the fluctuation of biomarkers in the absence of acute myocardial infarction in subjects with stable CAVS. This study will assess the biological variation of cardiac biomarkers in stable CAVS.

Study objective

To study the biological variation of cardiac biomarkers (e.g. cardiac troponin T and I, NT-pro-BNP, ST-2, Galectin-3) in clinically stable moderate aortic valve stenosis.

Study design

Observational study consisting of 7 short visits (at inclusion, 1 day, 1 week, 1 month, 3 months, 6 months and 1 year) at the same time of the day for blood sampling through venepuncture.

Study burden and risks

During the study, subjects will visit the hospital 7 times within 1 year (at inclusion, 1 day, 1 week, 1/3/6 months and 1 year). During the short visits (at inclusion, 3 months, 6 months and 1 year), subjects will complete a medical

questionnaire to assess their cardiovascular health status and venous sampling will be performed through venepuncture during every visit (7 times, 20 ml each time). The risks associated with the proposed study are low. A hematoma could occur as a result of the venepunctures.

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

Individuals (aged * 18 years) with clinically stable moderate aortic valve stenosis, defined by serial Doppler echocardiographic measurements of maximum transvalvular velocity (Vmax), mean pressure gradient (PGmean), and Aortic Valve Area (AVA) and a preserved ejection fraction (EF), will be recruited to participate in this study. Only subjects who are able to provide informed consent will be included.

Exclusion criteria

Subjects with severe aortic valve stenosis
Subjects with clinically progressive aortic valve stenosis
Subjects with documented atrial fibrillation in the last year. (subjects are allowed to have a history of atrial fibrillation)
Subjects with acute myocardial infarction in the last 6 months
Subjects with hospitalisation for heart failure in the last 6 months
Subjects with pulmonary embolism in the last 6 months
Subjects with chronic kidney disease (CKD)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	15-07-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-02-2016

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL53223.068.15

Study results

Date completed:	16-10-2017
Actual enrolment:	25