Quality of life in asymptomatic patients with severe aortic stenosis; up to 10-years of follow-up

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The main objective is to assess the long-term quality of life, as assessed with the SF-36v2* Health Survey, mortality and the cardiac functions as assessed with an echocardiogram in asymptomatic patients with severe aortic stenosis. Moreover,...

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

Summary

ID

NL-OMON43077

Source
ToetsingOnline

Brief title
AVARIJN 2

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: open heart surgery, severe aortic valve stenosis

Outcome measures

Primary outcome

Primary Objective(s): The primary objective is to determine the quality of life assessed with the SF-36V2* questionnaire in asymptomatic patients with severe aortic stenosis, the mortality (all-cause and specific cause) as well as the determination of the aortic valve function by an echocardiogram.

Secondary outcome

Secondary Objective(s): The secondary objective is to depict the emanated complications occurred during follow-up.

Study description

Background summary

Provide insight in aortic valve replacement in asymptomatic patients with severe aortic stenosis.

Study objective

The main objective is to assess the long-term quality of life, as assessed with the SF-36v2* Health Survey, mortality and the cardiac functions as assessed with an echocardiogram in asymptomatic patients with severe aortic stenosis. Moreover, complications during follow-up will be regarded as secondary objective.

Study design

hospital-based retrospective/ prospective cohort study

Study burden and risks

The expected burden is that of emotional, while filling the SF-36v2* Health Survey. However, organizational burden may also take place, (i.e. taking a day off, planning the travel route). We anticipate that there will be no adverse effect while performing the echocardiogram as the risk associated with an echocardiogram is negligible. Further data will be collected through the use of the hospital data systems, wherefore we are assured that this will not bring any harm to the patient. Moreover, patients may have benefit knowing that there is a potential chance in their cardiac hemodynamic as evaluated with an echocardiogram, which may lead to an altered, improved treatment strategy

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

- Adult patients, mentally competent and 18 years of age or older

- Inclusion in the AVARIJN study;* Echocardiographic criteria:
- Aortic valve area <=1 cm2
- Maximal trans aortic jet velocity >=4 m/s
- Aortic valve / left ventricular outflow tract velocity time integral ratio >=4;* Signed informed consent by patient and investigator

Exclusion criteria

Patients who are not able to give informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL57943.078.16