

Effects of Percutaneous Aortic Valve Implantation on sympathetic activity

Published: 09-10-2012

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The main objective is to assess the effects of TAVI on cardiac sympathetic activity.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON37473

Source

ToetsingOnline

Brief title

Effects of Percutaneous Aortic Valve Implantation on sympathetic activity

Condition

- Cardiac valve disorders

Synonym

aortic valve stenosis aortic valve narrowing

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aortic valve replacement, aortic valve stenosis, cardiac sympathetic activity

Outcome measures

Primary outcome

The change of cardiac sympathetic activity after aorta valve replacement.

Secondary outcome

This does not apply

Study description

Background summary

The precise effects of percutaneous aortic valve implantation (TAVI) on left ventricular function (LVF) and cardiac sympathetic activity have not been clarified yet. In the literature an observation has been described that the LVF improves after TAVI and after surgical aortic valve replacement (SAVR). This has been evaluated by echocardiography. The change of cardiac sympathetic activity assessed by 123I-MIBG scintigraphy has not been described before. This study is conducted as an observational study in which the effects on cardiac sympathetic activity after TAVI will be compared to the effects on cardiac sympathetic activity after SAVR. Our hypothesis is that by reducing the aortic pressure gradient after TAVI, the left ventricular dynamics will improve immediately after the procedure and will result in change of LVF and cardiac sympathetic activity.

Study objective

The main objective is to assess the effects of TAVI on cardiac sympathetic activity.

Study design

The study is designed as an observational investigation in which the effects on sympathetic activity will be investigated in patients undergoing TAVI or SAVR.

Study burden and risks

Participants will have no direct benefit from the study itself. The benefit of this study consists of the knowledge the investigators can gain from this study about the effects on cardiac sympathetic activity after TAVI compared to SAVR.

The possible risks that participants are exposed to are minor.

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

Severe symptomatic native aortic valve stenosis
Percutaneous or surgical aortic valve replacement

Exclusion criteria

Previous aortic valve replacement
Surgical aortic valve replacement combined with CABG or other valve surgery

Severe infection
Recent myocardial infarction or stroke
Enrolled in another investigational study

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Will not start

Enrollment: 60

Type: Anticipated

Ethics review

Approved WMO

Date: 09-10-2012

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	NL39028.018.11