Evaluation of the native aortic root preprocedure and prosthesis geometry post implantation by MSCT to guide prosthesis size selection before percutaneous aortic valve replacement

Published: 05-08-2009 Last updated: 05-05-2024

The objective is to assess the degree of under- and overexpansion and malapposition of the CRS after implantation, and to come with a proposal of sizing based upon observations made in a (large) prospective clinical data set-experience. For this...

| Ethical review | Approved WMO |
|-----------------------|-------------------------|
| Status | Recruiting |
| Health condition type | Cardiac valve disorders |
| Study type | Observational invasive |

Summary

ID

NL-OMON33154

Source ToetsingOnline

Brief title MSCT-PCVR

Condition

Cardiac valve disorders

Synonym artificial aortic valve

Research involving Human

1 - Evaluation of the native aortic root pre-procedure and prosthesis geometry post ... 14-05-2025

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MSCT, Percutaneous aortic valve replacement

Outcome measures

Primary outcome

To determine which dimensions of the aortic root are optimal to guide

prosthesis size selection

Secondary outcome

- The quantitative and qualitative assessment of the geometry and degree of

deformation of the PAVR prostheses with MSCT

- To investigate the association between aortic regurgitation (valvular and

para-valvular) post PAVR and 1) prosthesis sizing (degree of expansion,

asymmetry and apposition) and 2) position (depth of implantation)

Study description

Background summary

Up to 30 to 60% of patients with severe aortic stenosis do not receive surgical valve replacement because of perceived prohibitive risk. In these high risk patients, who are not treated surgically, medical therapy is associated with considerable morbidity and high mortality. Percutaneous aortic valve replacement (PAVR) is an increasingly important treatment alternative this patient group. However, much still needs to be learned about the percutaneous approach as reflected by the high complication rates so far reported albeit in high risk patients.

Study objective

The objective is to assess the degree of under- and overexpansion and malapposition of the CRS after implantation, and to come with a proposal of sizing based upon observations made in a (large) prospective clinical data set-experience. For this purpose, MSCT will be performed before and after implantation in patients with aortic stenosis who are scheduled for PAVR.

Study design

Prospective observational cohort study.

Study burden and risks

A MSCT is hardly seen as an invasive procedure

Contacts

Public Academisch Medisch Centrum

's-Gravendijkwal 230 3065 CE Rotterdam NL **Scientific** Academisch Medisch Centrum

's-Gravendijkwal 230 3065 CE Rotterdam NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

3 - Evaluation of the native aortic root pre-procedure and prosthesis geometry post ... 14-05-2025

Inclusion criteria

Patient scheduled for percutaneous Aortic valve replacement

Exclusion criteria

- Severe allergy to radiocontrast (previous anaphylaxis/angio-oedema)
- Severely irregular heart rhythm precluding diagnostic MSCT images
- Inability to breath hold for the duration of an MSCT scan

- Patients with severe renal impairment (estimated GFR below 20ml/min) will not be eligible for MSCT with contrast

Study design

Design

| Study type: Observational invasive | | |
|------------------------------------|-------------------------|--|
| Masking: | Open (masking not used) | |
| Control: | Uncontrolled | |
| Primary purpose: | Diagnostic | |

Recruitment

...

| NL | |
|---------------------------|------------|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 11-08-2009 |
| Enrollment: | 150 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|---|
| Date: | 05-08-2009 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

4 - Evaluation of the native aortic root pre-procedure and prosthesis geometry post ... 14-05-2025

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 CCMO **ID** NL26342.078.09