COmparison of iN situ structural integrity of TrAnsCatheter Heart Valves

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In this study we want to assess the structural THV integrity in situ and to identify the respective accommodation patterns of the different THV platforms and the interaction with the aortic root in situ.

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

Summary

ID

NL-OMON40932

Source
ToetsingOnline

Brief title
CONTACT study

Condition

- Cardiac valve disorders

Synonym
function and durability of aorticvalve, Structural integrity of transcatheter heart valve

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: Aotic root, TAVI, Valve durability, Valve performance

Outcome measures

Primary outcome

Primary Objective: MSCT and rotational angiography protocol is used to assess:

o Identify fractures in the framework

o Determine diameter of THV inflow, outflow and valve functioning segment and

assess circularity

o Determine Inflow and constraint segment perimeter and area

o Aortic root -THV relationship: circularity index of aortic root and THV

Secondary outcome

Secondary Objective:

o Transprosthetic gradient as assessed by Doppler TTE

o (paravalvular) aortic regurgitation by Doppler TTE

o Assess LV diameters/volumes

Study description

Background summary

Knowledge about in-situ Transcatheter Heart Valve (THV) appearance and structural integrity of the THV after implantation may provide insights in valve performance and durability. The aortic root can become circular or the THV can become ellipsoid. The impact on the long term is currently unsettled and requires extended follow up. Circularity of aortic annulus is defined using the eccentricity index (1 - Dmin/Dmax).

Study objective

In this study we want to assess the structural THV integrity in situ and to

identify the respective accommodation patterns of the different THV platforms and the interaction with the aortic root in situ.

Study design

Two-center prospective observational study: Erasmus MC and Amphia Breda.

Study burden and risks

Eligible patients who consent to participate in the CONTACT study will be invited for an additional MSCT scan and rotational angiography on top of the regular 6-month follow up at the outpatient clinic.
The major issue would be the exposure to clinical radiation. Yet, in this set of elderly patients with a limited life expectance, the clinical risks associated with radiation exposure will be negligible. Furthermore contrast exposure is limited to patients with a GFR > 40 mL/min. Pre- and posthydration protocols are scheduled for patients with GFR between 40 and 60 mL/min to prevent contrast induced nephropathy. The rotational angiography in the cathlab will evolve without contrast.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All Patients who undergo TAVI with the following THV are eligible for this study:
1. Medtronic Corevalve
2. Edwards Sapien and Sapien 3
3. BSC Lotus
4. St Jude Portico
5. Jenavalve THV
6. Direct Flow

Exclusion criteria

Exclusion criteria
1) GFR < 40 mL/min
2) No written informed consent
3) Previous stroke with residual neurological symptoms or dementia
4) Not native Dutch speaking

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2014

Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	10-06-2014
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	NL48123.078.14