Structural Integrity of the Medtronic Corevalve System after Transcatheter Aortic Valve Implantation

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Knowledge about long-term structural integrity of the MCS may support the current trends to expand TAVI technology to lower risk patient populations with longer life expectancy.

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

Summary

ID

NL-OMON38983

Source
ToetsingOnline

Brief title
TACT study

Condition

- Cardiac valve disorders

Synonym
corevalve function deformation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Medtronic,Medtronic Trading NL BV

Intervention

Keyword: aortic valve, Echografy, MSCT scan

Outcome measures

Primary outcome

- TTE, MSCT and Rotational Angiography protocols are used to assess

o Identify fractures in the MCS framework

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

assess circularity

o Determine changes in diameters with previous follow up MSCT/rotational

angiography when available

o Determine Inflow and constraint segment perimeter and area

o Depth of implantation/evidence for Corevalve migration over time

Secondary outcome

o Transprosthetic gradient as assessed by Doppler TTE

o Progression of (paravalvular) aortic regurgitation by Doppler TTE

o Assess LV diameters/volumes

o Changes in the parameters above over time

Study description

Background summary

Symptomatic severe aortic valve stenosis (AS) has a dismal prognosis.
Surgical aortic valve replacement (SAVR) is the standard treatment of care.
The first Transcatheter aortic valve implantation (TAVI) for the treatment of AS was conducted in 2002.
The Tavi technology is reserved for patients with severe AS and a (very) high surgical risk.

From trans-thoracic ultrasound after 2 years it becomes clear that at very high risk patients, the implantation of the TAVI has been very successful.
In the long term, the durability of the transcatheter system has to be demonstrated by evaluating the overall integrity of the system before to fit in patients with lower risk and longer life expectacy.
MSCT scan, transthoracal echo and rotational angiography may serve to evaluate the structural integrity by looking at stent fractures, expansion and eccentricity after four years

Study objective

Knowledge about long-term structural integrity of the MCS may support the current trends to expand TAVI technology to lower risk patient populations with longer life expectancy.

Study design

This is a single center study. Patients will be invited to the Thoraxcenter for a one-day visit to undergo 1) transthoracic echocardiography; 2) MSCT scan (without contrast); 3) Rotational Angiography.

Previous follow up TTE and MSCT will be used for comparison whenever available.

Survival status will be confirmed in the Civil Registry. Prof. Dr. de Jaegere will call the patients personally and explain the study design. If the patient agrees to participate, a patient information form including a consent form will be sent to the patient*s home address. After the patient will have sent back the signed informed consent form, the patient becomes eligible for the study and will be invited for a visit to the Thorax Center.

Study burden and risks

not applicable

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

Patients who underwent TAVI at least 4 years earlier will be approached by telephone to ask for participation in this study. Afterwards a formal invitation letter will be sent out.

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:	Recruitment stopped
Start date (anticipated):	12-08-2014
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	04-12-2013
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	NL45502.078.13