Valve Plane Tracking for TAVI; Automatic Valve plane tracking for Transcatheter Aortic Valve Implantation.

Published: 11-08-2014
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To evaluate the safety & efficacy of automatic valve plane tracking for the deployment of transcatheter bioprostheses.

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

Summary

ID

NL-OMON40644

Source
ToetsingOnline

Brief title
Valve Tracking

Condition

- Cardiac valve disorders

Synonym
Aortic stenosis, Aorticvalve 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: Aortic root, Aortic stenosis, TAVI, Valve positioning

Outcome measures

Primary outcome

- Volume of contrast.

- Valve deployment time.

- Depth of implantation of the valve (non-coronary and left aortic sinus) in mm

based upon contrast angiography after valve deployment.

Secondary outcome

- Mortality within the hospital or at 30 days whichever comes first.

- Renal insufficiency.

- Paravalvular aortic regurgitation.

Study description

Background summary

Transcatheter Aortic Valve Implantation (TAVI) is increasingly being used for patients with aortic stenosis who are ineligible or too high risk for surgical valve replacement (AVR). At variance with AVR, TAVI concerns catheter-based treatment on the beating heart without direct visualization of the target zone. For proper valve positioning, visualization of the base of the aortic root is done by fluoroscopy and contrast angiography with or without transesophageal echocardiography.
Correct positioning is mandatory for reasons of safety and efficacy in addition to the performance or execution of TAVI. It is conceivable that advanced imaging may be associated with increased safety and performance by * among others * less use of contrast, more correct final valve position and shorter procedure time. For that purpose, software has been developed that offers on-line continuous definition of the base of the aortic root by a single line connecting the nadir of the three aortic sinuses depicted on the X ray screen during TAVI. In the present study we seek to investigate the acute benefits of

such software.

Study objective

To evaluate the safety & efficacy of automatic valve plane tracking for the deployment of transcatheter bioprostheses.

Study design

Randomized open-label single-center pilot study.

Intervention

Not applicable.

Study burden and risks

Hypothetical benefits are reduction of the use of contrast during the procedure - with a subsequent lower rate of renal insufficiency - reduction of the procedure time through a reduction of the time of deployment and improving of the level of implantation.
As in any TAVI procedure, a risk is the misdeployment of the prosthesis.

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

1. Subject is * 18 years of age.
2. Subject is eligible for TAVI with a a CE approved transcatheter heart valve.
3. Subject understands the study requirements and the treatment procedures, and provides written informed consent.
4. Subject is capable of returning to the study hospital for all required follow-up.

Exclusion criteria

1. The aortic root cannot be defined by the software.
2. Subject did not receive a valve because of aborted procedure.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20

Type:	Anticipated

Ethics review

Approved WMO Date:	11-08-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-09-2014
Application type:	Amendment
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	NL48323.078.14