Edwards SAPIEN periprosthetic leakage evaluation versus Medtronic CoreValve in tranfemoral aortic valve implantation: the ELECT trial

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

Summary

ID

NL-OMON41687

Source
ToetsingOnline

Brief title
ELECT

Condition

- Cardiac valve disorders

Synonym
Aortic valve stenosis, narrowing of the native aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Mozaiek beurs van de NWO

Intervention

Keyword: Edwards SAPIEN, Medtronic CoreValve, Percutaneous aortic valve implantation, Periprosthetic aortic regurgitation

Outcome measures

Primary outcome

The primary endpoint is post-TAVI periprosthetic aortic regurgitation measured

with 3DTEE and new developed special software.

Secondary outcome

Secondary objectives of this study include: investigating the value of

different imaging modalities in evaluating periprosthetic regurgitation after

TAVI and studying the difference in clinical endpoints according to VARC-2

definitions and quality of life after TAVI between two available aortic valve

prostheses.

Study description

Background summary

Transcatheter aortic valve implantation (TAVI) is a good alternative treatment for patients with severe aortic valve stenosis with similar mid-term success rates as compared to surgery. Periprosthetic aortic regurgitation after TAVI remains an important limitation of this technique. Moderate to severe periprosthetic aortic regurgitation occurs in 15-45% of the cases and it is an independent predictor of mortality after TAVI. Little is known about potential differences in severity of periprosthetic aortic regurgitation among different types of aortic valve prosthesis.

Study objective

The current randomized study aims to evaluate potential differences between the

Edwards SAPIEN bioprosthesis and the Medtronic CoreValve® system with main focus on periprosthetic aortic regurgitation and additional focus on other clinical and imaging endpoints. Primary objective of this study is to investigate the difference in the severity of periprosthetic aortic regurgitation, measured with 3-dimensional transesophageal echocardiography (3DTEE), between patients undergoing the implantation of the Edwards SAPIEN bioprosthesis versus patients receiving the Medtronic CoreValve® bioprosthesis.

Study design

single-center, randomised controlled trial. 108 patients will be randomly allocated in a one-to-one ratio to undergo transcatheter implantation of either an Edwards SAPIEN (n=54) or a Medtronic CoreValve® bioprosthesis (n=54). Randomization will be performed using sealed envelopes.

Intervention

All TAVI will be performed via the femoral artery. One group of patients will receive the balloon expandable Edwards SAPIEN bioprosthesis and the other group will receive the self-expanding Medtronic CoreValve®.

Study burden and risks

Patients participating in this study are planned to undergo a TAVI procedure in our centre. Which one of the two available types of bioprosthesis they will receive, is normally randomly chosen by the operator. Both aortic valve bioprostheses, Edwards SAPIEN and Medtronic CoreValve® are safe and are approved in Europe. Both valve bioprostheses are used on a regular basis in our center and our interventional cardiologists are experienced with implanting both of them (Utrecht data show 0% in hospital mortality with both CoreValve and Edwards in 2012 and 2013). Thus, based on the available knowledge randomization for the type of bioprosthesis does not bring additional procedural risk for the patients. As part of this study, patients will undergo a series of additional investigations, including 3DTEE, MRI and 24-hour urine collection. 3DTEE represents a valuable and generally safe diagnostic tool for the evaluation of cardiac performance and the function of the valve prosthesis and is routinely performed in this institution. It is essential in the quantified assessment of periprosthetic regurgitation. Possible risks associated with 3DTEE include infection and oral or esophageal mucosal injury. During the MRI made at follow up, no contrast agent will be given to the patient. Therefore, when safety guidelines are followed properly, MRI poses no known health risks to the patient and produces no physical side effects. There are no risks related to the 24-hour urine collection and the quality of life questionnaire. Using the additional MRI, the urine examination and the quality of live questionnaire, extra information will be gained in regard to the

consequences of TAVI procedure for other organs of the body and the quality of life of patients undergoing this procedure. Using this extra information, we might be able to introduce measures for improving the safety of TAVI and the outcome of patients undergoing this procedure.

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)Patient is 18 years of age or older and diagnosed with severe symptomatic aortic stenosis, judged inoperable or at high surgical risk (EuroSCORE < 15%) and deemed eligible for TAVI by a consensus among a cardiologist and a cardiac surgeon (heart-team), 2) Or a patient who is considered to be operable by the heart-team, but who chooses to undergo TAVI instead of conventional surgery, 3) Annulus diameter *18 and *28, 4) Patients who undergo a transcatheter aortic valve implantation via the transfemoral approach

Exclusion criteria

1) Patients with contraindications for transesophageal echocardiography (TEE)
2) Patients unable to give informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2013
Enrollment:	108
Type:	Actual

Medical products/devices used

Generic name:	Aortic valve bioprostheses: Edwards SAPIEN versus Medtronic CoreValve
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	15-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	08-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-09-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
ClinicalTrials.gov	NCT01982032
CCMO	NL43116.041.13