Preoperative CT-imaging with patient-specific computer simulation in transcatheter aortic valve replacement: a randomized controlled trial.

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

Summary

ID

NL-OMON56189

Source
ToetsingOnline

Brief title
GUIDE-TAVR

Condition

- Cardiac valve disorders

Synonym
aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Aortic valve stenosis, Computer simulation, FEops HEARTGuide, Transcatheter aortic valve replacement

Outcome measures

Primary outcome

Mild to severe PVR

Secondary outcome

New CD (new-onset left bundle branch block, new-onset atrioventricular block)

requiring permanent pacemaker (PPM) implantation.

Preoperative and final selected valve size, target and final implantation

depth, change of preoperative decision, failure to implant valve, MACCE

composite endpoint, quality of life, healthcare costs and cost-effectiveness,

FFR measurement (on standard MSCT and CAG).

Study description

Background summary

Combining routine preoperative CT imaging with patient-specific computer modelling predicts the interaction between different sizes of transcatheter aortic valve replacement (TAVR) devices at different implantation depths and the patient*s unique anatomy (including post-implantation deformation) allowing preoperative evaluation of the risk for paravalvular leakage (PVR) and conduction disorders (CD).

Study objective

The objective of this randomized controlled trial (RCT) is to evaluate whether pre-operative CT-imaging with advanced computer modelling and simulation (FEops HEARTguide* (FHG)) adequately predicts procedural outcomes in TAVR procedures, whether it leads to changes of preoperative decisions and whether or not this

leads to improved outcome in TAVR procedures and reduction in health care costs.

Study design

Single center, randomized controlled, open-label, pilot trial.

Intervention

In patients randomized to arm 1, FEops HEARTGuide will be added to routine preoperative CT imaging. Results of the computer modelling will be discussed with TAVR implanting team prior to the procedure. Patients randomized to arm 2 will only have routine preoperative CT imaging.

Study burden and risks

FEops HEARTguide* is designed to predict the interaction between the TAVR device and the patient*s unique anatomy, including post-implantation deformation, allowing physicians to assess the risk for aortic regurgitation and conduction abnormalities. Especially in patients with complex anatomy such as BAV, it could be of great value to be able to predict the possible complications in order to identify patients at risk for these unfavourable outcomes. This additional information may improve the outcomes of the TAVR patients included in the FHG arm of our study population.
Unfortunately, since FEops HEARTGuide is not on the market yet for the SAPIEN transcatheter heartvalves (Edwards) and the PORTICO Valve (Abbott), the patients that are chosen to be more suitable to one of these valves by the physicians will have to be excluded. As a consequence, the findings of our study will not be applicable for all current available TAVR valves.
The risks related to the use of FEops HEARTGuide for TAVR patients are negligible, due to multiple reasons. First of all, the physician chooses the optimal treatment on the basis of both simulation results and clinical aspects. This means that FEops HEARTGuide does not give the *best option*, but only simulates the valve type(s) picked by the physician in multiple sizes and for multiple implantation depths per size. After FEops HEARTGuide has provided these options to the physician, they will be evaluated by the physician and valued as acceptable or not. Therefore, FEops HEARTGuide is an add-on to the standard pre-procedural planning and not a replacement.
The only extra burden for each patient consists of the quality of life questionnaires, which will take up up to 20 minutes for each patient.

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

- Primary symptomatic severe aortic valve stenosis (defined as an aortic valve area of <1.0cm2 and either a mean valve gradient of at least 40mmHg or a peak velocity of at least 4.0 m/s)
- Accepted for TAVR, either by transfemoral, transsubclavian or transapical access as determined by the Heart Team and additionally the dedicated TAVR-team.
- Plan to implant one of the following TAVR heart valves for which FEops HEARTguide* is available:
o CoreValve*, Evolut* R, and Evolut* PRO and Evolut* PRO+ valves (Medtronic)
o ACURATE neo* Aortic Valve System (Boston Scientific) (ACURATE neo 2* will be available for FHG later this year)
- Informed consent

Exclusion criteria

- Previous surgical aortic valve replacement

- Permanent pacemaker at baseline
- Emergency procedure
- Poor CT image quality (disabling computer-simulation), for example because of motion artifacts due to the presence of other implanted devices affecting the region of interest
- Patient who did not agree to the informed consent and/or refused to participate
- Patient unable to understand the informed consent/study

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2022
Enrollment:	354
Type:	Actual

Medical products/devices used

Generic name:	FEops HEARTGuide
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-02-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	21-02-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77697.100.21