Transcatheter Aortic Valve Replacement With the Medtronic Transcatheter Aortic Valve Replacement System In Patients at Low Risk for Surgical Aortic Valve Replacement

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Demonstrate that the safety and effectiveness of the Medtronic TAVR system as measured by rates of all-cause mortality or disabling stroke at two years is non-inferior to SAVR in the treatment of severe aortic stenosis in subjects who have a low…

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Other condition
Study type	Interventional research applied for the first time in human subjects

Summary

ID

NL-OMON53079

Source
ToetsingOnline

Brief title
Medtronic TAVR System In Patients at Low Risk for SAVR

Condition

- Other condition
- Cardiac valve disorders

Synonym
severe Aortic stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic
Source(s) of monetary or material Support: Medtronic

Intervention

- Medical device

Keyword: low risk for surgical aortic valve replacement (SAVR), severe aortic stenosis, Transcatheter Aortic Valve Replacement (TAVR) System

Explanation

N.a.

Outcome measures

Primary outcome

All-cause mortality or disabling stroke at 2 years

Secondary outcome

Safety
1. Composite of death, disabling stroke, life-threatening bleed, major vascular
complication, or AKI (II or III) at 30 days
2. New permanent pacemaker implantation at 30 days
3. Prosthetic valve endocarditis at one year
4. Prosthetic valve thrombosis at one year
5. All stroke (disabling and non-disabling) at one year
6. Life-threatening bleed at one year
7. Valve-related dysfunction requiring repeat procedure at one year
Effectiveness
1. Valve-related dysfunction (moderate or severe stenosis or regurgitation) at
one year
2. Quality of Life as assessed by Kansas City Cardiomyopathy (KCCQ) at one year
3. Repeat hospitalization for aortic valve disease at one year

Study description

Background summary

Over the past ten years, transcatheter aortic valve replacement (TAVR) has

emerged as a transformative
technology for the management of severe aortic stenosis. TAVR has become the standard of care for
patients with aortic stenosis who are inoperable or at extreme risk for surgical aortic valve replacement,
and is the preferred alternative for patients with severe aortic stenosis who are at high risk for surgical
aortic valve replacement. Following Cribier*s first implantation in 2002, TAVR has evolved to become a
standard procedure at specialized heart centers worldwide, and is now performed with only moderate
sedation rather than general anesthesia in many patients.
TAVR was initially performed in patients at the highest risk for surgical aortic valve replacement, but data
indicate that patients at intermediate risk are increasingly being treated with TAVR.

In addition to the main study, subjects may volunteer in the LTI sub-study to help determine the frequency (how often) leaflet thickening and reduced leaflet motion are found in tissue valves after transcatheter or surgical aortic valve replacement. Participation in this sub-study is optional.

Study objective

Demonstrate that the safety and effectiveness of the Medtronic TAVR system as measured by rates of all-cause mortality or disabling stroke at two years is non-inferior to SAVR in the treatment of severe aortic stenosis in subjects who have a low predicted risk of operative mortality for SAVR

The LTI sub-study is being done to gather information on how often leaflet thickening and reduced leaflet motion occur in tissue valves after transcatheter or surgical aortic valve replacement.

Study design

Multi-center, international, prospective, randomized, interventional, pre-market. Subjects will be randomized on 1:1 basis to either TAVR with the Medtronic TAVR system or to SAVR.

The LTI sub-study will involve approximately 300 subjects at up to 100 hospitals worldwide who will be followed for one year after implant procedure as part of the sub-study.

Intervention

Transcatheter Aorta Valve replacement (TAVR)

Surgical Aorta Valve Replacement (SAVR)

Study burden and risks

As with any TAVR or SAVR procedure, there are risks associated with participation in this trial. However,
the risks to a patient for participation in this trial are not materially different than those a patient would
incur if they underwent TAVR or SAVR outside of this trial,see protocol page 70-72

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Trial sites

Trial sites in the Netherlands

Erasmus MC, Universitair Medisch Centrum Rotterdam
Target size: 15

St. Antonius Ziekenhuis
Target size: 15

Catharina-ziekenhuis
Target size: 15

Listed location countries

Australia, France, Netherlands, Switzerland, Japan, Canada, New Zealand, United States

Eligibility criteria

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

Inclusion criteria

Heart Team consensus patient has < 3% predicted risk of mortality at 30 days for SAVR
* Severe aortic stenosis, defined as :
* Symptomatic aortic stenosis
Aortic valve area <= 1.0 cm2 (or aortic valve area index of <= 0.6 cm2/m2), OR mean
gradient >= 40 mmHg, OR maximal aortic valve velocity >= 4.0 m/sec by transthoracic echocardiography
* Asymptomatic aortic stenosis:
- Very severe aortic stenosis with an aortic valve area of <=1.0 cm2 (or aortic valve area index of <=0.6 cm2/m2), AND maximal aortic velocity >= 5.0 m/sec, or mean gradient >= 60 mmHg by transthoracic echocardiography, OR
- Aortic valve area of <=1.0 cm2 (or aortic valve area index of <=0.6 cm2/m2), AND a mean gradient >= 40 mmHg, or maximal aortic valve velocity >= 4.0 m/sec by transthoracic echocardiography, AND an exercise tolerance test that demonstrates a limited exercise capacity, abnormal BP response, or arrhythmia OR
- Aortic valve area of <= 1.0 cm2 (or aortic valve area index of <= 0.6 cm2/m2), AND mean gradient >= 40 mmHg, or maximal aortic valve velocity >= 4.0 m/sec by transthoracic echocardiography, AND a left ventricular ejection fraction < 50%.
* Indicated for SAVR with a bioprosthesis

Exclusion criteria

Bicuspid aortic valve identified by echocardiography, MDCT, or Magnetic Resonance
Imaging
Significant ascending aortopathy

Study design

Design

Study phase:	N/A
Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Safety

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	04-01-2018
Enrollment:	60
Duration:	120 months (per patient)
Type:	Actual

WORLD

Recruitment status:	Recruitment started
Start date (anticipated):	01-03-2016
Enrollment:	1200
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	Transcatheter Aortic Valve replacement system
Registration:	No

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO Date:	09-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-05-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-06-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-09-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-12-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	12-05-2025
Application type:	Amendment
Review commission:	MEC-U

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	NCT02701283
CCMO	NL60501.100.17
Research portal	NL-008763