Enable® Aortic Sutureless bioprosthesis Evaluation (EASE study): A post-market release non-interventional study

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The objective is to collect additional data on the clinical outcomes (surgical data, safety and clinical performance) of the Medtronic Enable® Aortic Bioprosthesis in *real world* patients. The collected data will be used to improve aortic valve...

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

Summary

ID

NL-OMON39896

Source
ToetsingOnline

Brief title
EASE Enable

Condition

- Cardiac valve disorders

Synonym
aortic valve disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiovascular diseases, Heart valve diseases, Sutureless

Outcome measures

Primary outcome

- Hemodynamic performance of the Medtronic Enable aortic bioprosthesis at discharge, within 6 months following implantation, 1 year and annually thereafter up to 5 years post-implant.

- New York Heart Association (NYHA) classification

- Safety: includes all Serious Adverse Events (SAEs) and (Serious) Adverse Device Effects (ADEs/SADEs).

These variables will be evaluated by comparison with the baseline data and with published data in the literature.

Secondary outcome

Not applicable.

Study description

Background summary

The Medtronic Enable® sutureless aortic bioprosthesis (model 6000) was first implanted in February 2007. The Medtronic Enable® sutureless aortic bioprosthesis is commercially available and has received CE-mark in December 2009.

The Enable® aortic bioprosthesis is developed for aortic valve replacement (AVR) and is intended for use in patients whose aortic valvular disease is sufficiently advanced to warrant replacement of their native valve with a prosthetic device. The usual conditions of advanced disease are aortic stenosis, aortic insufficiency or a combination of the two.

The Enable aortic bioprosthesis consists of the following:
• The 3f Aortic Bioprosthesis* Model 1000, (commercially available in Europe) assembled from three equal sections of equine pericardial material that have been cross-linked with formulations of low concentration glutaraldehyde under specific parameters of time, pH and temperature. This fixation process preserves the collagen architecture of the pericardial material, minimizes the immunogenic potential of the xenogeneic tissue and preserves flexibility and strength.
• A self-expanding Nitinol frame covered with polyester fabric on the inflow aspect

The self-expanding Nitinol frame, allows for a quick fixation of the Enable valve in the aortic annulus without suturing (sutureless-concept). Consequently, the Enable implant time will be significantly reduced, which will shorten the cardiopulmonary bypass time.

Clinical experience has shown that aortic valve replacement with Medtronic Enable aortic bioprosthesis is safe, that the hemodynamic performance of the Enable bioprosthesis is very good and that the operation time is significantly shortened due to the quick fixation of the Enable in the aortic annulus.

Study objective

The objective is to collect additional data on the clinical outcomes (surgical data, safety and clinical performance) of the Medtronic Enable® Aortic Bioprosthesis in *real world* patients.

The collected data will be used to improve aortic valve replacements for other patients.

Study design

Non-interventional, non-randomized, prospective, multi-center post-market release (PMR) study.
The data will be collected at discharge, within 6 months following implantation, 1 year and annually thereafter up to 5 years post-implant.

Study burden and risks

The Medtronic Enable aortic bioprostheses used in this study, has CE-mark and are released for distribution at the moment of study start. Medtronic is not aware of any significant problems with this product. In the study, the products will be used in accordance with their labeling, therefore no risks other than the risks typically associated with a routine device implantation and follow-ups are anticipated.

In addition subjects are treated according to general clinical practice, so no extra tests and follow-ups are required. Therefore, no additional risks are associated with participation in this study.

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 with aortic valve stenosis, aortic valve insufficiency or a combination of the two.
2. Patient requires replacement of his/her native aortic valve with a bioprosthesis with or without concomitant procedures.
3. Patient is above the minimum age as required by local regulations to be participating in a clinical study.
4. Patient is willing to return to the implant site for follow-up visits.
5. Patient has been adequately informed of this clinical study and is willing to sign the

patient Data Release Form.

Exclusion criteria

1. Patient requires replacement of two or more valves.
2. Patient who underwent previous aortic valve replacement (AVR).
3. Patient with native bicuspid aortic valve.
4. Patient with active endocarditis or other systemic infection.
5. Patient dilatation of the ascending aorta, deformations or irregular aortic annulus or ascending aorta geometry as seen via preoperative imaging.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-04-2013
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	20-11-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NCT01720342
CCMO	NL42349.058.12

Study results

Date completed:	01-11-2016
Actual enrolment:	65

Summary results
Trial is onging in other countries