Medtronic PERIcardial SurGical AOrtic Valve ReplacemeNt Pivotal Trial (PERIGON) Long-term Follow-Up. A multi-center, non-randomized trial to determine the safety and effectiveness of the Model 400 aortic valve bioprosthesis in patients with aortic valve disease.

Published: 21-03-2014
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To evaluate the safety and effectiveness of the Model 400 Aortic Valve Bioprosthesis. LTFU:To evaluate the long-term safety and effectiveness of the Avalus Bioprosthesis.

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

Summary

ID

NL-OMON54842

Source
ToetsingOnline

Brief title
PERIGON Pivotal Trial LTFU

Condition

- Cardiac valve disorders

Synonym

Aortic Valve Replacement, new heart valve

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aortic Valve, Model 400, PERIGON

Outcome measures

Primary outcome

1. Safety:

a. Thromboembolism

b. Valve Thrombosis

c. Hemorrhage

d. Paravalvular leak

e. Endocarditis

f. Hemolysis

g. Structural valve deterioration

h. Non-structural dysfunction

i. Reintervention

j. Explant

k. Death

2. Effectiveness:

a. Hemodynamic Performance Metrics

b. New York Heart Association Functional Classification

Secondary outcome

N/A

Study description

Background summary

Medtronic, has developed a new heart valve, called Model 400 made of bovine (cow) tissue. Bovine pericardial aortic heart valves have good left ventricular mass regression (remodeling), freedom from structural valve deterioration (SVD), and a high rate of survival, which may offer better early hemodynamics (low transvalvular pressure gradients and increased effective orifice area) and ease of use (low stent profiles). For these reasons, bovine pericardial heart valves hold the majority of the stented aortic heart valve market. Therefor Medtronic developed this valve.

De PERIGON LTFU is a longitudinal investigational clinical trial with long-term follow-up of subjects who are enrolled in the PERIGON Pivotal Trial, who received the Avalus valve, and who consent to participate in long-term follow up. The subjects will be followed up to 12 years post-implant.

Study objective

To evaluate the safety and effectiveness of the Model 400 Aortic Valve Bioprosthesis.

LTFU:
To evaluate the long-term safety and effectiveness of the Avalus Bioprosthesis.

Study design

This is a prospective, interventional, non-randomized, worldwide, multi-center trial.

Intervention

aortic valve replacement via open-heart surgery

Study burden and risks

Study Procedures:

After the implantation there will be six follow up visits planned. These visits need to be performed in the hospital who implanted the valve. During these follow up visits the perfomance of the Model 400 will be checked via echo. Additionaly there will be an ECG made, bloodsamples will be taken and they will inform to the current health and the medication.
Besides the yearly follow up visits the patient will be contacted by phone 1.5 and 2.5 year after the valve implantation. Also during these phone call follow ups the patient will be asked for current health and the use of medication.

LTFU:
Subjects will undergo evaluation annually from 6 years through 12 years (±60 days) post-procedure.
Evaluations will be performed either in-person at the study center (years 7, 10, and 12) or via telephone
call (years 6, 8, 9, and 11). The following evaluations will be completed, and data collected on the
electronic case report forms (eCRFs):
• NYHA classification (may be performed via phone in years 6, 8, 9, and 11 per institutional standard
practice)
• 12-Lead electrocardiogram (ECG) (only required at years 7, 10, and 12)
• Transthoracic echocardiography (TTE) (only required at years 7, 10, and 12)
• Safety endpoint events
• All reportable Adverse Events and Device Deficiencies
• Relevant medications
• Vital status

Risks:
Every surgery contains risks. General surgical risks include problems from the anesthesia, side effects from the medication used, bleeding at the operation site, heart attack and infections.
The main risk with the Model 400 aortic valve bioprosthesis is like the risk of approved heart valves. This means that the artificial heart valve may have or cause a problem at some time after the operation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patient has moderate or greater aortic stenosis or regurgitation, and there is clinical indication for replacement of their native or prosthetic aortic valve with a bioprosthesis, with or without concomitant procedures, which are limited to any of the following:
i. LAA ligation
ii. CABG
iii. PFO closure
iv. Ascending aortic aneurysm or dissection repair not requiring circulatory arrest
v. Resection of a sub-aortic membrane not requiring myectomy
2. Patient is geographically stable and willing to return to the implanting site for all follow-up visits
3. Patient is of legal age to provide informed consent in the country where they enroll in the trial
4. Patient has been adequately informed of risks and requirements of the trial and is willing and able to provide informed consent for participation in the clinical trial

LTFU:
1. Subject is a participant in the PERIGON Pivotal Trial and is implanted with the Avalus valve;
2. Patient is of legal age to provide informed consent in the country where they enroll in the trial;

3. Patient has been adequately informed of risks and requirements of the trial and is willing and able to provide informed consent for participation in the clinical trial;
4. Patients must be geographically stable and willing to return to the implanting site for all follow-up visits.

Exclusion criteria

1. Patient has a pre-existing prosthetic valve or annuloplasty device in another position or requires replacement or repair of the mitral, pulmonary or tricuspid valve 2. Patient has had previous implant and then explant of the Model 400 aortic valve bioprosthesis 3. Patient presents with active endocarditis, active myocarditis or other systemic infection 4. Patient has an anatomical abnormality which would increase surgical risk of morbidity or mortality, including: • Ascending aortic aneurysm or dissection repair requiring circulatory arrest • Acute Type A aortic dissection • Ventricular aneurysm • Porcelain aorta • Hostile mediastinum • Hypertrophic obstructive cardiomyopathy (HOCM) • Documented pulmonary hypertension (systolic >60mmHg) 5. Patient has a non-cardiac major or progressive disease, with a life expectancy of less than 2 years. These conditions include, but are not limited to: • Child-Pugh Class C liver disease • Terminal cancer • End-stage lung disease 6. Patient has renal failure, defined as dialysis therapy or GFR<30 mL/min/1.73 m2 7. Patient has hyperparathyroidism 8. Patient is participating in another investigational device or drug trial or observational competitive study 9. Patient is pregnant, lactating or planning to become pregnant during the trial period 10. Patient has a documented history of substance (drug or alcohol) abuse 11. Patient has greater than mild mitral valve regurgitation or greater than mild tricuspid valve regurgitation as assessed by echocardiography 12. Patient has systolic EF<20% as assessed by echocardiography 13. Patient has Grade IV Diastolic Dysfunction 14. Patient has documented bleeding diatheses 15. Patient has had an acute preoperative neurological deficit or myocardial infarction and has not returned to baseline or stabilized >=30 days prior to enrollment 16. Patient requires emergency surgery LTFU: 1. Subjects who have had an explant of the Avalus valve prior to the long-term follow up study period; 2. Subjects who have had a valve in valve prior to the long-term follow up study period; 3. Subject unable or unwilling to return for study follow-up visits.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	24-09-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	23-10-2019

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	06-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	07-09-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-02-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT02088554
CCMO	NL45419.058.13