Perceval Sutureless Implant Vs Standard Aortic Valve Replacement

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

Summary

ID

NL-OMON47376

Source
ToetsingOnline

Brief title
PERSIST-AVR study

Condition

- Cardiac valve disorders

Synonym
heartvalve steno insufficiency, heartvalve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Group Italia S.r.l.
Source(s) of monetary or material Support: Sorin Group Italia Srl

Intervention

Keyword: biologic aortic valve replacement, Perceval, sutureless

Outcome measures

Primary outcome

The primary endpoint is freedom from MACCE (composite endpoint of all cause death, myocardial infarction, stroke, and valve re-intervention) at one year based on CEC adjudication

Secondary outcome

1. Surgical time

a. Cross clamp time during index procedure

b. Cardiopulmonary bypass time during index procedure

2. Normalized Consumption Index and reduced Normalized Consumption Index, including resource consumption items such as (but not limited to):

a. Operative room time,

b. Duration of ICU/CCU and total hospital stay

c. Incidence of specific serious adverse events as defined in Appendix 3

d. Blood transfusion(s)

3. Quality of life questionnaire

b. At 1 month and 1 year post surgery

4. Intraprocedural and periprocedural serious adverse events regardless of relationship with the device within 72 hours

5. All valve and procedure relevant serious adverse as specified in VARC-2 guidelines

a. Early safety at 30 days

b. Clinical efficacy after 30 days

c. Time related valve safety: SVD, endocarditis, thrombosis, thromboembolic events (excluding stroke), and bleeding annually up to 5 years

6. Serious device related adverse events up to 5 years

7. Freedom from MACCE at 2, 3, 4 and 5 years of follow up

8. Pacemaker implantation and cause up to 1 year

9. Valve hemodynamics (PPM, PPG, MPG; DVI, EOA, LVOT, AI, PVL, EROA) assessed by site-reported echocardiographic parameters preoperatively, at discharge, between 1-3 month, 1 year, 3 year and 5 year.

10. Valve hemodynamics (PPM, PPG, MPG; DVI, EOA, LVOT, AI, PVL, EROA) in a reduced cohort of patients assessed by core lab echocardiographic parameters preoperatively, at discharge, between 1-3 month, 1 year, 3 year and 5 year.

Study description

Background summary

The Perceval sutureless aortic heart valve (Perceval valve) is a bioprosthesis manufactured with bovine pericardium and assembled on a Nitinol stent. The Perceval valve is designed to offer an alternative to stented and stentless biological valves. A special feature of the device is that it is self-anchoring and does not require sutures to be fixed to the implant site.
Due to the lack of prospective, randomized comparison data between sutureless valve and standard aortic valve, this randomized study is planned to demonstrate, as primary endpoint, the non inferiority of Major Adverse Cardiac and Cerebrovascular (MACCE) events at one year

Study objective

The primary objective of this trial is to test the safety and efficacy of Perceval valve versus standard sutured stented bioprosthetic aortic valves among the intended trial population.
The secondary objective is to compare all relevant device and subject demographics, procedural and hospital discharge, short and long-term data, as described in the secondary endpoints section

Study design

This is a prospective, randomized (1:1), stratified non blinded multi-center, international study

A maximum of 1234 patients are planned to be enrolled, but accrual may stop earlier at approximately 900 or 1050 subjects.

Patients will be evaluated at different time intervals:
- pre-operatively (including CT scan)
- At implant (including transesophageal echocardiography- TEE)
- 1 month after implant (hospital discharge or within 30 days postoperatively)
- Between 1 to 3 months postoperatively
- At 1 year (postoperatively between 11 and 13 months) and
- Annually until study completion (2 and 4 year visit can be done via phone)

A transthoracic echocardiographic (TTE) assessment, physical examination (including NYHA assessment and ECG) and blood tests will be performed at every clinical visit.

Intervention

Besides the heartvalve replacement procedure/operation (standard treatment/practice), a transthoracic echocardiographic (TTE) assessment, physical exam (including NYHA and ECG) and blood tests will be performed at every visit. A transesophageal echocardiography (TEE) assessment will be

performed at implant.

Study burden and risks

The most obvious benefit from implant of a bioprosthetic valve is overall improvement in patient condition as a result of improved heart valve function. The risks and discomforts associated with the use of the Perceval valve are not expected to exceed the frequency and severity of those reported with other aortic bioprosthethic valves.
Minimization of the risks will be accomplished by selection of patients who are appropriate candidates for implant with a bioprosthesis.

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. The subject has an indication for treatment by valve replacement with a bioprosthesis according to the IFU, through either full sternotomy or mini-sternotomy.
2. The subject has aortic valve disease that can be treated with a commercially available Perceval valve size, based on preoperative CT-scan.
3. The subject has:
a. critical aortic valve area defined as an initial aortic valve area of *1.0 cm2 or aortic valve area index < 0.6 cm2/m2
AND
b. Mean gradient > 40mmHg or Vmax > 4m/sec by resting echocardiogram or simultaneous pressure recordings at cardiac catheterization [or with dobutamine stress, if subject has a left ventricular ejection fraction (LVEF) <55%] or velocity ratio < 0.25;
4. The subject is symptomatic due to aortic stenosis with functional class of NYHA II or higher.
5. The subject has signed the informed consent.
6. The subject is of legal minimum age.
7. The subject will be available for postoperative follow-up beyond one year.

Exclusion criteria

1. The subject has a contraindication for treatment by the Perceval valve or by a bioprosthetic aortic valve as stated in the IFU.
2. The subject has aneurismal dilation or dissection of the ascending aortic wall.
3. The subject is scheduled for concomitant procedures other than CABG, myectomy with or without aortic annulus enlargement.
4. The subject has congenital bicuspid (i.e. Sievers type 0) or unicuspid aortic valve.
5. Anatomical structures not suitable for Perceval valve such as: aortic root enlargement, where the ratio between the diameter of the sino-tubular junction and the annulus diameter is > 1.3.
6. The subject has a prosthetic heart valve in any position, including mitral valve repair.
7. The subject had a stroke or myocardial infarction (STEMI and NSTEMI) within 30 days prior to the planned valve implant surgery.
8. The subject has active endocarditis, myocarditis, or sepsis.
9. The subject is in cardiogenic shock manifested by low cardiac output and needing hemodynamic support.
10. The subject is allergic to nickel alloys.
11. The subject is already included in another clinical trial that could confound the results of this clinical investigation.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Biologic heartvalve
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-10-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-06-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT02673697
CCMO	NL56524.068.16