Perceval S valve clinical trial for extended CE-mark

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

Summary

ID

NL-OMON34868

Source
ToetsingOnline

Brief title
CAVALIER study

Condition

- Cardiac valve disorders

Synonym
Aortic valve stenosis/insufficiency, occlusion/leakage of aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Sorin Biomedica CRM SRL
Source(s) of monetary or material Support: Sorin Biomedica Cardio S.r.l.

Intervention

Keyword: Aorta heart valve insufficiency and stenosis, Bioprosthesis, Obtaining CE-mark, Perceval S-valve

Outcome measures

Primary outcome

Safety endpoints:

- Safety of the Perceval S-valve will be evaluated based on pre-determined adverse events related to cardiac valve replacement. Morbidity and valve-relatedness will be determined according to specific guidelines for reporting morbidity after valve surgery.

Effectiviness endpoints:

Effectiviness of the Perceval S-valve will be determined by evaluation of hemodynamic performance to assess valve function of NYHA-classification to assess improvement in patient condition.

Secondary outcome

The secondary endpoints of the clinical investigation are:

- Assessment of mortality and morbidity rates at discharge (or 30 days if the patient is still hospitalized) and at 3-6 months after implant;
- Evaluation of the effectiveness of Perceval S valve in terms of improvement of clinical status assessed by means of NYHA-classification at discharge (or 30 days if the patient is still hospitalized), 3-6 months after surgery;
- Evaluation of the effectiveness of Perceval S valve in terms of haemodynamic performance through echocardiography at discharge (or 30

days if the patient is still hospitalized) and 3-6 months after surgery;

- Mortality and morbidity as well as haemodynamic parameters will be assessed.

Study description

Background summary

Perceval S is a prosthetic valve comprising a stabilised functional component in bovine pericardium, assembled to a super-elastic metal alloy armature (Nitinol stent). A special feature of the device is that it doesn*t need sutures to be fixed to the implant site. This function is accomplished by the armature, which therefore has the dual role of valve support and secure anchorage to the aortic root.

The sponsor has completed a Pilot-Study (First In Man) aimed at demonstrating the 30-days safety of the Perceval S-valve in high risk patient.
Based on these results, the sponsor designed a new trial aimed at:
- confirming the safety and performance results in a larger patient population;
- obtaining CE-mark with limited indication.
This study is currently ongoing.

Study objective

The primary objective of this clinical investigation is to assess the safety and effectiveness of the Perceval S-valve at 12 months after implantation when used to replace a diseased or dysfunctional aortic valve or aortic valve prosthesis.

The safety will be assessed in terms of percentage incidence of mortality and morbidity at 12 months after implant.
The effectiveness will be assessed in terms of:
- Improvement of clinical status by mean of the NYHA-classification at 12 months after implant.
- echocardiography parameters to research the haemodynamic improvement.

Study design

Cavalier study is a prospective, non-randomised. multicentre, European clinical trial.

A minimum of 300 patients (a minimum of 15 patient in 8 centers) will be followed to a minimum of one year postimplant. As necessary, additional patients will be implanted and followed until the requirement of 800

valve-years of experience is achieved.

Patients will be evaluated at each of the following time intervals:
· pre-operatively,
· at implant,
· in the early postoperative period (at hospital discharge or within 30 days postoperatively),
· in the late postoperative period (between 3 and 6 months postoperatively),
· at 1 year (between 11 and 13 months postoperatively),
· annually until study completion.

Intervention

Beside the implantation (standard treatment) a Transthoracic echocardiography (TTE) assessment, clinical examination (incl. NYHA-classification) and haematological analysis will be performed during each visit. A transesophageal echo (TEE) will also be performed intraoperatively.

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 het use of the Perceval S valve are not expected to exceed the frequency and severity of those reported with other bioprosthetic valves. However, the implant of the Perceval-S valve can possibly lead to a slightly higher risk of a paravalvulair leak. Theoratically, there is a minor change of valve migration. Minimization of the risks will be accomplished by selection of patients who are appropriate candidates for implant with a bioprosthesis. As a result of the sutureless implant procedure of the Perceval S-valve prosthesis, benefits from reduced cross-clamp time and consequently duration of extracorporeal circulation are expected.

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

Subjects of age 65 (or older) years;
Subjects with aortic valve stenosis or steno-insufficiency;
Subjects in which preoperative evaluation indicated the need for native or prosthetic aortic valve replacement with a biological prosthesis;

Exclusion criteria

Subjects involved in any other clinical study for drugs or devices;
Subjects with a previously implanted Perceval S prosthesis, within the clinical study, that requires replacement;
Subjects with previous implantation of valve prostheses or annuloplasty ring not being replaced by the study valve;
Subjects requiring simultaneous cardiac procedures, apart from septal myectomy and/or coronary by-pass;
Subjects who require double or multiple valve replacement or repair;
Subjects with aneurysmal dilation or dissection of the ascending aortic wall;
Subjects with active endocarditis, myocarditis;
Subjects with congenital bicuspid aortic valve;
Subjects with myocardial infarction < 90 days before the planned valve implant surgery;
Subjects with known hypersensitivity to nickel alloys.

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):	22-09-2010
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	Perceval S heart valve
Registration:	No

Ethics review

Approved WMO Date:	28-05-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2010
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	NL31492.060.10