An Observational, Prospective Evaluation of the Trifecta* Valve Protocol No: CS05002TV

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Study Purpose and ObjectivesStudy PurposeTo confirm the clinical safety and effectiveness of the Trifecta valve by establishing associated adverse event rates, clinical status as indicated by NYHA functional classification, hemodynamic performance,...

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

Summary

ID

NL-OMON33582

Source
ToetsingOnline

Brief title
Evaluation Trifecta* Valve

Condition

- Cardiac valve disorders

Synonym
aortic valve disease

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical

Source(s) of monetary or material Support: St. Jude Medical

Intervention

Keyword: Aortic valve, Evaluation, Observational, Trifecta

Outcome measures

Primary outcome

Safety Endpoints

1. Morbidity and mortality are evaluated by early rates, linearized rates, Kaplan-Meier life tables and Cox Proportional Regression for the following adverse events: hemolysis (clinically significant), nonstructural dysfunction, paravalvular leak, structural deterioration/failure, major bleeding events (whether or not related to drug therapy), anticoagulant related hemorrhage, embolism (valve-related), endocarditis, valve thrombosis, reoperation, explant, and death (all and valve-related).

2. The primary analysis is to compare the observed event rates to the OPC. When any of the sequential analyses demonstrate the posterior probability that the event rate is less than 2*OPC is larger than 0.80 and the posterior probability that the event rate is less than the OPC is at least 0.20 for all 6 classifications then the Trifecta valve will be considered successful (reference Primary Statistical Analysis section of Appendix F).

Effectiveness Endpoints

1. Percentage of patients in each NYHA functional classification at baseline (preoperatively) and at follow-up intervals, and the percentage of patients improving, not changing, or worsening in NYHA functional classification at each

follow-up time point.

2. Mean, standard deviation, minimum and maximum values for mean gradient, peak gradient, effective orifice area, effective orifice area index, cardiac output, cardiac index, and performance index will be evaluated. Percentage of patients for the incidence/severity of aortic insufficiency as determined by echocardiography by location (central and paravalvular leak) will be provided. All echocardiography data will be presented by valve size.

3. Mean, standard deviation, minimum and maximum values for hemoglobin, hematocrit, white blood cell count, red blood cell count, and plasma free hemoglobin will be evaluated. Normalized data will be based on blood normals from the blood core lab. In addition, the percentage of blood values that are below, within, or above the specified normal range will be evaluated by valve size.

Secondary outcome

nvt

Study description

Background summary

To provide an additional bioprosthetic valve choice to physicians, St. Jude Medical has developed the Trifecta valve. The Trifecta valve is a tri-leaflet stented pericardial valve designed for supra-annular placement in the aortic position. The valve leaflets are fabricated from bovine pericardial tissue and the valve incorporates a porcine pericardial tissue covering on the stent to prevent contact between the valve leaflets and the polyester covered stent. The Trifecta valve is processed using Linx* anticalcification technology. The leaflets of the Trifecta valve are uniquely mounted on the outside of the valve stent providing a large opening area which results in superior hydrodynamics as compared to a currently marketed stented pericardial valve

(reference Table 1). The porcine pericardial tissue covering on the Trifecta valve stent minimizes the potential for wear by allowing only tissue-to-tissue contact. Additionally, the Linx* anticalcification treatment of the Trifecta valve may aid in minimizing tissue calcification, which is a primary failure mode in bioprostheses.10

Table 1: In-Vitro Pulsatile Flow Results
Trifecta Valve
(n=5 per valve size) Currently Marketed Stented Pericardial Valve (Control Valve)
(n=1 per valve size)
Aortic Valve Size Mean Pressure Gradient
(mm Hg) EOA (cm2) Mean Pressure Gradient
(mm Hg) EOA (cm2)
19 mm 8.0 1.8 15.6 1.3
21 mm 6.0 2.2 -- --
23 mm 4.1 2.7 -- --
25 mm 2.3 3.5 4.5 2.6
27 mm 2.0 3.9 -- --
29 mm 1.7 4.4 2.5 3.5
Note: The pulsatile flow results were from measurements conducted at a pulse rate of 70 beats/min, a nominal cardiac output of 5.0 liters/min, and a back pressure of 100mm Hg.

Study objective

Study Purpose and Objectives

Study Purpose
To confirm the clinical safety and effectiveness of the Trifecta valve by establishing associated adverse event rates, clinical status as indicated by NYHA functional classification, hemodynamic performance, and hematology analysis.

Safety Objective
To establish adverse event rates as compared to a set of Objective Performance Criteria (OPC).

Effectiveness Objectives
1. To characterize patient NYHA functional classification status.
2. To characterize the hemodynamic performance of the valve, as per echocardiography.

Study design

Study Design Overview

The clinical investigation is a multi-center, multi-country, prospective, non-randomized, observational study without concurrent or matched controls, designed to evaluate the safety and effectiveness of the Trifecta valve. A maximum of 120 subjects requiring aortic valve replacement will be implanted at a maximum of 3 investigational sites in Europe. The sample size is based on late patient-years of follow-up with a minimum of 400 late patient-years experience required. A comparable study is being conducted in the United States and Canada. Data from a maximum of 7 Canadian sites and 18 U.S. sites may be used.
This study will be conducted in accordance with the requirements provided in ISO 5840: 2005(E).
Patients satisfying inclusion/exclusion criteria and have signed informed consent will undergo a preoperative baseline evaluation that includes NYHA functional classification determination, blood tests, and a general clinical assessment.
Those patients who are successfully implanted with the Trifecta valve will have an echocardiogram, blood tests, and a general clinical assessment conducted at discharge or 30 days post-implant (whichever occurs first). Additional follow-up at 6 months, 12 months, and annually thereafter will include an echocardiogram, NYHA classification determination, blood tests, and a general clinical assessment. All patients will have annual follow-up visits until the CE mark for the Trifecta valve has been approved or denied by the applicable regulatory agencies or as otherwise requested by regulators, study investigators, or the Data Monitoring Committee.

Study burden and risks

Potential benefits to the subjects may include, but are not limited to, relief of valvular stenosis and/or incompetence and related symptoms. A subject may benefit from the improved longevity of the valve, due to the Linx* treatment of the Trifecta valve (if the Linx* treatment is proven effective). In addition, similar benefits may accrue to future subjects through experience gained in this investigation.

Subjects participating in this study are not expected to be at any higher or additional risk than those commonly associated with the implant of a prosthetic heart valve. There are risks with any heart valve replacement. These may include, but are not limited to angina, bleeding events (including perioperative bleeds), cardiac arrhythmias, death (valve and non-valve related), embolism, endocarditis, explant, heart failure, hemolysis, hemolytic anemia, myocardial infarction, nonstructural dysfunction, paravalvular leak, regurgitation, reoperation, stroke, structural deterioration, valve thrombosis, valvular pannus or other serious adverse events

Animal studies conducted on the Trifecta valve demonstrated survival rates comparable to a currently marketed stented pericardial valve (control valve). These results provide evidence of safety and show promise for long-term

clinical durability (reference Appendix J).
Additionally, durability testing was conducted on the Trifecta valve utilizing SJM's accelerated life testers in accordance with the test criteria specified in the Food and Drug Administration (FDA) Heart Valve Guidance and ISO 5840. Durability testing conducted on the Trifecta valve was carried out to 200 million cycles simulating 5 years of use. As a reference, three control valves were also exposed to the same conditions; Carpentier-Edwards Pericardial Bioprothesis Model 2700 (aortic sizes 19, 25, and 29mm).
The durability test results demonstrate that there was no significant wear of the Trifecta valve out to 200 million cycles. One control valve failed durability testing prior to 200 million cycles and two passed.

For burden: see study design for follow up visits for the patients.

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 requires aortic valve replacement. (Note: patients undergoing concomitant procedures, e.g. coronary artery bypass grafting, or valve repair, are eligible for this study).
2. Patient is legal age in host country.
3. Patient (or legal guardian) has given written informed consent for participation prior to surgery.
4. Patient is willing to undergo all study procedures and adhere to data collection and follow-up requirements.

Exclusion criteria

1. Patient is pregnant or nursing (women of child bearing potential must have a documented negative pregnancy test within one week prior to surgery).
2. Patient already has a prosthetic valve(s) at a site other than the aortic valve.
3. Patient requires concomitant replacement of the tricuspid, pulmonary, or mitral valve.
4. Patient has an inability or is unwilling to return for the required follow-up visits.
5. Patient has active endocarditis (patients with previous endocarditis must have two documented negative blood culture results prior to enrollment).
6. Patient has had an acute preoperative neurological event defined as patient has not returned to baseline or has not stabilized 30 days prior to the planned valve implantation surgery.
7. Patient is undergoing renal dialysis.
8. Patient has a documented history of substance abuse within one year of enrollment.
9. Patient is currently participating in the study of an investigational drug or device, or the patient was previously participating in an investigational drug study and has not completed a 30-day wash out period.
10. Patient had the Trifecta valve implanted as part of this study, but then had the device explanted.
11. Preoperative evaluation indicates other significant cardiovascular abnormalities such as aortic dissection or ventricular aneurysm.
12. Patient has a life expectancy less than two years.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2009
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Trifecta Valve
Registration:	No

Ethics review

Approved WMO Date:	22-12-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-09-2009
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
ClinicalTrials.gov	NCT00727181
CCMO	NL24476.100.08