Trifecta GT Post Market Clinical Follow-up

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

Summary

ID

NL-OMON45515

Source
ToetsingOnline

Brief title
Trifecta GT PMCF

Condition

- Cardiac valve disorders

Synonym
aortavalve replacement - disease of the aortavalve

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Performance, post CE approval, Safety, Trifecta GT

Outcome measures

Primary outcome

Freedom from surgical valve replacement or transcatheter valve-in-valve implantation at 5 years post implant.

Secondary outcome

* Freedom from all-cause mortality at 5 years post implant

* Freedom from valve related mortality at 5 years post implant

* Freedom from Structural Valve Deterioration (SVD) at 5 years post implant

* Freedom from surgical valve replacement or transcatheter valve Implantation due to SVD at 5 years post implant

* Valve hemodynamic performance (e.g. left ventricular ejection fraction, mean and peak gradients, aortic insufficiency and effective orifice area via any available/performed echocardiograms) at pre-discharge, 6 months, 3 years and 5 years post implant.

Study description

Background summary

SJM*s Trifecta family of aortic heart valves is used in patients with valvular heart disease. Valvular heart disease is characterized by abnormal heart valve function with interruption of normal blood flow through the heart. This may result in symptoms such as fatigue, weakness, shortness of breath, chest pain and/or heart palpitations. There are two types of heart valve disease: narrowed heart valve and leaky heart valve. A narrowed heart valve (also known as valvular stenosis) is characterized by a narrowed valve opening, requiring the heart to work hard to pump blood. A leaky heart valve (also known as valvular

regurgitation) is characterized by a valve that does not close tightly. If the valve cannot fully close, blood can leak backwards across the valve causing the heart to work harder, resulting in less blood flow to the body. Some patients may have a mixture of both types of heart valve disease involving one or more of the valves.

Valvular heart disease can be congenital or may be acquired as a result of various diseases or infections, including rheumatic fever and endocarditis. Other causes of valvular heart disease may include, but are not limited to, atherosclerosis, cardiomyopathy, hypertension, aortic aneurysms, and connective tissue diseases.

Valvular heart disease is responsible for nearly 93,000 valve related operations and 20,000 deaths each year in the United States. It is also a contributing factor for another 42,000 deaths each year. The majority of these cases involve disorders of the aortic valve (63%).1 Specific aortic valvular disorders include: aortic stenosis, aortic regurgitation, or a combination of the two, with aortic stenosis being the leading indication for aortic valve replacement in adults.

Patients with either aortic stenosis, regurgitation, or both may remain asymptomatic for many years. However, after the onset of symptoms (angina, syncope, or dyspnea), the average survival is less than 2 to 3 years.2 Aortic valve replacement (AVR) appears to be the most effective treatment for these patients.2

For patients that need an aortic valve replacement, the Trifecta Glide Technology (GT) aortic valve is one option. The Trifecta GT aortic heart valve is based on the design of the predicate Trifecta valve and has minor modifications to the sewing cuff and holder for the purpose of enhancing ease of use and implantability. The sewing cuff was modified to have less drag when passing sutures, less susceptibility to deformation, and improved fluoroscopic appearance. The holder was also modified in the following ways:
1. lower profile by moving the holder legs away from the valve stent posts to reduce bulkiness and improve access to the sewing cuff for knot tying/seating,
2. adding stent backstops on the inside of the holder to protect the stent from potential deformation,
3. changing the holder from a click-in design to a screw-in design to reduce overall bulkiness and accidental disengagement.

The Trifecta valve received approval in Europe on 4 March 2010, in Canada on 18 October 2010 and in the United States on 20 April 2011. The Trifecta GT valve was approved in Europe on 1 February 2016, in Canada on 8 July 2016 and in the United States on 24 April 2016.

Study objective

The objective of this study is to evaluate the safety and performance of the Trifecta* GT valve through 5 year follow-up in a prospective, multi-center, real-world setting. This study is intended to satisfy post-market clinical follow-up requirements of CE Mark in Europe. This study is sponsored by St. Jude Medical.

Study design

This study is a multi-center, prospective 5 year study of approximately 350 subjects intended to be implanted with a SJM Trifecta GT valve. It will be conducted in approximately 35 sites worldwide.

Enrollment is expected to be completed within 1 year and follow-up will be 5 years for each enrolled subject. Therefore, the total duration of the study is expected to be 6 years.

To ensure an adequate number of subjects at each site, no individual site may enroll more than 10% of the maximum sample size (n=35 subjects) without prior approval from the sponsor.

Study burden and risks

The Trifecta valve received approval in Europe on 4 March 2010. The Trifecta GT valve was approved in Europe on 1 February 2016. This aortavalve is commercially released in The Netherlands. The Trifecta GT-heart valve is an improvement on the Trifecta valve. There is already more that 5 years follow-up data available on the Trifecta heart valve. The risk for the patient is comparable to any other aorta vavle replacement surgery.

This study is intended to satisfy post-market clinical follow-up requirements of CE Mark in Europe.We evaluate the safety and performance of the Trifecta* GT valve through 5 year follow-up in a prospective, multi-center, real-world setting. This study is according to the requirements of the Notified Body.

Obtaining more scientific data on the aortic heart valve outweigh the additional burden for the patient. The additional burden is 3 extra TTE at 3 additional study visits.

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. Subject is a candidate for surgical aortic valve replacement per current guidelines and is intended to be implanted with a St. Jude Medical Trifecta GT valve.
2. Subject is of legal age in the country where the subject is enrolled.
3. Subject must be willing and able to provide written informed consent to participate in this study.
4. Subject must be willing and able to comply with all follow-up requirements.

Exclusion criteria

1. Subject undergoes a concomitant procedure of mitral or tricuspid valve replacement at the time of the Trifecta GT valve implantation surgery.
2. Subject has contraindication for cardiac surgery.
3. Subject is pregnant. Pregnancy will be assessed by the subject informing the physicians.
4. Subject has active endocarditis (subjects who have previously experienced endocarditis must have two documented negative blood culture results while off antibiotic therapy prior to the valve implantation surgery).
5. Subject has had a stroke or transient ischemic attack within 6 months prior to the planned valve implantation surgery.

6. Subject is undergoing renal dialysis.
7. Subject has a history of active drug addiction, active alcohol abuse, or psychiatric hospital admission for psychosis within the prior 2 years.
8. Subject has a documented thrombus in the left atrium or left ventricle at the time of the valve implantation surgery.
9. Subject has a left ventricular ejection fraction < 30%.
10. Subject previously enrolled in the Trifecta GT PMCF study and withdrawn (a subject cannot be enrolled twice in this study).
11. Preoperative evaluation indicates other significant cardiovascular abnormalities such as aortic dissection or ventricular aneurysm.
12. Subject has a life expectancy less than 2 years.

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):	02-11-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	08-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-08-2018

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	NL60274.100.16