A Clinical Study of the CardiAQ* Transcatheter Mitral Valve Implantation (TMVI) System (Transapical Delivery System)

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

Summary

ID

NL-OMON41986

Source
ToetsingOnline

Brief title
CardiAQ TMVI System

Condition

- Cardiac valve disorders

Synonym
leaky heart valve, mitral regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: CardiAQ Valve Technologies, Inc.

Source(s) of monetary or material Support: CardiAQ

Intervention

Keyword: implantation, mitral valve, regurgitation, transcatheter

Outcome measures

Primary outcome

The primary endpoint is the percentage of Subjects with a composite Major Adverse Event (MAE) at 30 days for the following events: cardiovascular mortality, myocardial infarction, disabling stroke and conversion to surgery per VARC definitions.

Secondary outcome

Safety Endpoints

* Freedom from composite MAE at three (3), six (6) and twelve (12) months

* Individual 30-Day event rates for the following: cardiovascular mortality, procedure related death, non-cardiovascular mortality, myocardial infarction, disabling stroke, non-disabling stroke, transient ischemic attack (TIA), conversion to surgery, life-threatening, major and minor bleeding, stages 1-3 acute kidney injury and major and minor vascular complications per VARC definitions

* Number of events and percentage of Subjects for all individual adverse events related to the System or procedure at 30 days, three (3), six (6) and twelve (12) months

Hemodynamic Efficacy

Hemodynamic improvement at 30 days, three (3), six (6) and twelve (12) months compared to Baseline. The Bioprosthesis will be assessed by echocardiography

for reduction in mitral regurgitation by quantitative measures (e.g. PISA, vena contracta width, EROA, regurgitant volume and fraction), as well as overall MR grade.

Functional Improvements

Functional improvements at 30 days, three (3), six (6) and twelve (12) months as compared to Baseline for New York Heart Association (NYHA) classification, Exercise tolerance (Six Minute Walk Test) and Quality of Life evaluation (Kansas City Cardiomyopathy Questionnaire).

Acute Device/Procedural Success

Acute device/procedural success is defined as meeting all the following: successful transapical access, successful delivery and deployment of the Bioprosthesis and retrieval of the Catheter, correct positioning of the Bioprosthesis at the proper anatomical location to achieve Grade 2+ or less MR following the implant procedure, no clinically-significant LVOT obstruction (pressure gradient * 20 mmHg) and no bleeding requiring re-intervention for apical repair.

Study description

Background summary

Today*s standard of care for mitral valve replacement is open-heart surgery. But, open-heart surgery can involve serious risks for patients who are older, have other heart disease, or have general health problems.
CardiAQ Valve Technologies, Inc. has developed the CardiAQ TMVI System to replace a patients mitral valve without the need for open-heart surgery. Instead, the CardiAQ Valve is implanted using a procedure called a transcatheter mitral valve implantation (TMVI)

Study objective

The primary objective of the study is to generate safety and performance data for the CardiAQ* Transcatheter Mitral Valve Implant System with the Transapical Delivery System to support a future marketing application for the treatment of moderate to severe mitral valve regurgitation in patients who are considered high or extreme risk for mortality and morbidity from conventional open heart surgery.

Study design

Clinical safety and performance study - multi-center, prospective, single-arm, non-randomized study without concurrent or historical controls

Intervention

Transcatheter Mitral Valve Implantation

Study burden and risks

As the CardiAQ TMVI System is an investigational device, there may also be additional risks or side effects, which are unknown at this time. Possible outcomes of these risks and side effects could include reoperation, surgical removal of the device, permanent disability or death.

The information that is learned from this study may benefit other patients who have your same health condition. It is possible that the collection of information on the performance and safety of the device will allow early detection of unforeseen problems.
The CardiAQ Valve may provide one or more of these benefits:
* Mitral valve replacement without open heart surgery
* Mitral regurgitation reduction or elimination that improves the blood flow through your heart
* Improved quality of life by reducing some of your physical limitations
* Reduced discomfort or tiredness when performing certain physical activities

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

General
1. * 65 years old.
2. Willing and able to comply with all required follow-up evaluations and assessments.
3. Subject or authorized representative has read the informed consent, agrees to comply with the requirements, and has signed the informed consent to participate in the study.
Heart Failure Status
4. New York Heart Associate Classification * III
5. Left Ventricular Ejection Fraction * 30%.
6. Mitral regurgitation (MR) * Grade 3+ (moderate/severe, or severe) using the AHA/ACC 2014 Guidelines for the Management of Patients with Valvular Heart Disease (as published in Circulation March 3, 2014).
7. STS mortality score * 8% or determined to be high or extreme surgical risk by a Cardiac Surgeon.
8. Hemodynamically stable while on heart failure medication for at least 30 days before the procedure.
Anatomical
9. Left atrial height * 4 cm.
10. Left Ventricular End Systolic Diameter (LVESD) * 6 cm.
11. Mitral valve major (single axis) annulus diameter meets the range of 36-39.5 mm.
12. Angle of mitral valve axis to aortic valve axis is deemed unlikely to be obstructive by the Investigator.

13. Suitable left ventricular anatomy for delivery system access per the medical opinion of the Investigator.

Exclusion criteria

General
1. Currently participating in another investigational drug or device study.
2. Need for emergent or urgent surgery for any reason.
3. Any condition that, in the opinion of the Investigator, could interfere with Subject participation, confound the study results or interfere with study compliance.
Anatomical
4. Lack of chordal support of the mitral valve (i.e., ruptured papillary muscle or secondary chords).
5. Severe calcification of any component of the mitral valve, including one or both of the mitral leaflets.
6. Myocardial infarction within the previous 6 weeks.
7. Intra-cardiac thrombus, mass or vegetation.
8. Need for native aortic or pulmonic valve replacement.
Existing Co-morbidities
9. Any prior surgical or transcatheter repair (excluding balloon valvuloplasty) or replacement of the mitral valve.
10. Pre-existing mechanical prosthetic valve in the aortic position.
11. History of cardiac transplantation.
12. Any history of pulmonary embolism.
13. Clinically significant, untreated coronary artery disease.
14. Percutaneous coronary intervention within the prior 30 days.
15. Contraindication to Transesophageal/Transoesophageal Echocardiography (TEE/TOE).
16. Active endocarditis or rheumatic heart disease within the previous 3 months.
17. Refractory, unstable angina.
18. Significant cerebral vascular event within the previous 3 months.
19. Atrial fibrillation with uncontrolled heart rate (> 100 bpm).
20. Hemodynamic instability (systolic pressure < 90 mmHg without afterload reduction, cardiogenic shock or the need for inotropic or intra-aortic balloon pump support).
21. Untreatable hypersensitivity or contraindication to any of the following:
* Aspirin and Clopidogrel and Ticlopidine, OR
* Heparin and Bivalirudin, OR
* Warfarin, Nitinol Alloys (nickel and titanium), contrast media, glutaraldehyde or bovine tissue.
22. Bleeding diathesis or coagulopathy, or Subject refuses blood transfusion.
23. Active peptic ulcer or GI bleeding.
24. Severe pulmonary hypertension (> 55 mmHg) and severe COPD (FEV1/FVC < 70% and FEV1 < 50% predicted FEV1).
25. Severe right ventricular systolic dysfunction.
26. Severe tricuspid valve regurgitation (Grade 4+)
27. Pulmonary function FEV1 (< 750 cc).

28. Subject has severe kidney disease with
* Creatinine level > 194 µmol/L (2.2 mg/dL) OR
* eGFR * 30 mL/min.
29. Liver disease, cirrhosis of the liver or significantly abnormal liver function test results.
30. Significant uncorrected endocrinology deficiency.
31. Co-morbid condition(s) that, in the opinion of the Investigator, limit life expectancy to < 12 months.
32. Active infections that requires antibiotic therapy (if temporary illness, Subjects may enroll 2 weeks after discontinuation of antibiotics). Subjects must be free from infection prior to treatment. Any required dental work should be completed a minimum of 3 weeks prior to treatment.

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):	16-11-2015
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	CardiAQ Transcatheter Mitral Valve Implant and Transapical Delivery System
Registration:	No

Ethics review

Approved WMO

Date:	01-06-2015

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL52340.078.15