EVALUATION OF THE MINIMALLY INVASIVE VENTOUCH* SYSTEM IN THE TREATMENT OF FUNCTIONAL MITRAL VALVE REGURGITATION (FMR)

Published: 05-10-2016
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* Confirm device safety and performance* Confirm implant procedure and therapy adjustment procedure safety and performance

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

Summary

ID

NL-OMON44030

Source
ToetsingOnline

Brief title
VenTouch* System First-In-Man Continuation Study

Condition

- Cardiac valve disorders

Synonym
mitral valve insufficiency, secondary mitral regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Mardil Medical
Source(s) of monetary or material Support: industry (Mardil Medical)

Intervention

Keyword: functional mitral regurgitation

Outcome measures

Primary outcome

* Evaluate mean reduction in MR, and freedom from grade 3 and 4 MR at 6 months post-therapy adjustment, as measured by an echocardiographic core lab

* Evaluate Serious Adverse Event (SAE) rates at 6 months post-therapy adjustment

Secondary outcome

* Evaluate Serious Adverse Event (SAE) rates

* Evaluate mean reduction in MR, and freedom from grade 3 and 4 MR, as demonstrated by quantitative measures

* Quantitative assessment of reverse remodeling based on change in LVEDD, LVEF

* Improvement in patient symptoms as assessed by the NYHA functional class

* Improvement in Six-Minute Walk and Minnesota Living with Heart Failure Questionnaire

Study description

Background summary

The VenTouch* system was developed leveraging technology from two separate medical devices. The first was a modified version of the Mardil BACE* device. This device was comprised of a silicone band that encircled the base of the heart and an array of four to five independently inflatable silicone chambers within the band. The second device was the Acorn Cardiovascular CorCap device. This device was a polyester mesh that was placed around the heart to reduce dilated heart stresses and encourage reverse remodeling.
The VenTouch* System is designed to reshape the base of the heart to bring the

mitral valve leaflets into better coaptation. By doing so, it brings the mitral valve leaflets closer, allowing proper closure of the valve, and reducing or eliminating MR. There is provision of support to the ventricular myocardium below the annulus as well as the annulus, so the VenTouch* System may allow long-term ventricular remodeling with positive impact on the functionality of the mitral valve.

Study objective

* Confirm device safety and performance
* Confirm implant procedure and therapy adjustment procedure safety and performance

Study design

This is a prospective, multi-center, single-arm study to show safety and efficacy of the VenTouch System for treatment of functional mitral valve regurgitation [FMR] in up to 15 subjects deemed eligible per assessment by the Inclusion/Exclusion Criteria listed below.

Up to 15 subjects at sites in Canada, France, Netherlands, Czech Republic and Malaysia.
Follow-up at implant, therapy adjustment, 1, 3, 6 (efficacy and safety endpoint), and 12, 24 and 36 months post-therapy adjustment.

Intervention

The VenTouch* System is designed to be deployed over the epicardial surface of the heart, covering the surface of both ventricles, from the atrioventricular (AV) groove to the cardiac apex, in such a way that it will be positionally while not resulting in compression of the coronary arteries and veins. The implanting surgeon selects the device size based on preoperative estimates and intraoperative confirmation of subject heart size with a dedicated inter-operative sizing tool and then chooses the appropriately sized VenTouch* System. During the implant procedure, the tool is manipulated to insure that the hem of the implant lies adjacent to the AV groove, and the rotational orientation is such that the silicone balloon is adjacent to the outer surface of the heart overlying the midpoint of the posterior aspect of the leaking mitral valve. The balloon is inflated and the results on mitral valve geometry and function are observed echocardiographically. Once optimal implant and bladder position are confirmed, the bladder is deflated and the device is allowed several weeks to heal in order to insure positional stability.

At least 30 days after implant, after fibrous tissue ingrowth, the silicone chamber is reinflated. The silicone chamber once refilled with saline applies pressure on the posterior mitral valve decreasing the septal lateral dimension

of the valve and increasing leaflet coaptation, with a corresponding reduction in mitral regurgitation. The VenTouch* System can be adjusted as needed via subcutaneous access such that the size of the chamber can be increased or decreased over time based on grade of mitral regurgitation defined by echocardiogram or other imaging methodology.

Study burden and risks

Consented subjects will undergo additional screening to ensure that they qualify to get the device. Once consented subjects medical history, labs, medications, physical exam, 12-lead ECG, transesphogeal echo, Cardiac CT will be collected and sent to a subject selection committee for review. Further baseline assessments such as 6 minute hall walk and Minnesota living with heart failure questionnaire will be completed if subject qualifies for the study. The subject will then be scheduled for an implant and will be hospitalized for the implant. Thirty days post implant the subjects will come back to the hospital for a therapy adjustment visit. After this the subjects will be seen at 1, 3, 6, 12, 24, and 36 month visits. There will be an echo performed at each visit and another cardiac MRI at 6 months. HF assessments, 6 minute hallwalk and Minnesota Living with HF questionnaire will be collected at 3, 6, 12, 24, and 36 months.

Certain risks may be associated with the treatment(s), the associated procedures, and the surgical procedures performed, including other heart surgery procedures. These risks include death, bleeding, infection, stroke, blood clotting problems or clots, fluid around the lungs or heart, pneumonia, heart attack, abnormal heart rhythm, kidney failure, allergic reactions to medications, worsening heart valve function, stitches blocking the blood vessels in the heart, persistent remnants of MR, low rate of blood flow through the heart, or heart failure.
All efforts will be made to minimize the risks in this trial by selecting investigators who are experienced and skilled in trial procedures, by clearly defining inclusion/exclusion criteria to ensure only the appropriate subjects are enrolled and by ensuring that treatment and follow-up of the subjects are consistent with current medical practices. Additional risks for participation in this study will be minimized by subject selection, center selection and training, and monitoring to ensure proper study conduct and management.
The risks associated with a normal cardiothoracic surgery associated with anesthesia, surgical and related procedures include:
* Bleeding
* Reoperation
* Infection
* Neurologic [stroke, TIA, coma]
* Pulmonary embolism
* Pulmonary edema
* Pneumonia
* Renal compromise

* Peripheral thromboembolism
* Blood coagulation abnormalities [anticoagulant complications; hemolysis]
* Myocardial infarction
* Tamponade
* Cardiac arrhythmias
* Death
* Allergic response to anesthesia or medications
* Readmission within 30 days

The investigational device may still have unknown side effects. Additional device-related adverse events may include:
* Inadequate/incomplete repair of the valvular and subvalvular structures
* Compression or kinking of the circumflex coronary artery by the hem of the device
* Residual or recurrent regurgitation
* Thromboembolism
* Potential for adhesions which will likely make Coronary Artery Bypass Grafting (CABG) impossible to perform
* Malfunction of the device due to distortion at implant or physical or chemical deterioration of components
* Hemolysis
* Low cardiac output
* Heart failure
* Infection
* Failure or degeneration of the subject*s natural valvular apparatus
* Need for reoperation or device removal
* Death

The VenTouch* System is designed to provide support to and remodeling of the base of the heart through precisely applied pressure on the epicardial surface. The device reduces the septal lateral dimension of the mitral annulus, improving leaflet coaptation and facilitating proper closure of the valve, and reduction or elimination of MR. The VenTouch* System may allow long-term ventricular remodeling with positive impact on the functionality of the mitral valve. It is also possible that the subject may receive no benefit from the VenTouch* System.

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. Adults *18 years of age
2. Symptomatic FMR of grade moderately severe to severe (3 to 4) with structurally normal leaflets (preferably with echocardiographic evidence of EROA> 0.20 cm2)
3. NYHA Class II to IV
4. Left Ventricular Ejection Fraction (LVEF) 20%-50%
5. Treatment with optimal guideline-directed medical therapy for heart failure for at least 30 days. Subjects must be receiving a beta blocker for 3 months and an ACE-I or ARB for one month unless, in the investigator*s opinion, the subject is intolerant to beta blockers, ACE-I or ARB. Beta blockers and ACE-I (or ARB) doses should be stable for one month prior to study entry. Stable is defined as no more than a 100% increase or a 50% decrease in dose.
6. Subjects with a Class I indication for CRT implant according to current guidelines should have CRT implant prior to entry into the study. Subjects who have existing CRT implants may be included in the study if the implant has been in place for at least 90 days.
7. Left Ventricular End Diastolic Diameter (LVEDD) of 55 to 80 mm as determined by transthoracic echocardiography.
8. Subject is willing and available to return for study follow-up
9. Subject or legal representative understands and provides signed informed consent for participation in study
10. Acceptance of subject for trial enrollment after review of all subject baseline data by Study Selection Committee

Exclusion criteria

1. Life expectancy of less than 12 months due to conditions other than cardiac status
2. Identified need for any cardiovascular surgery
3. Untreated clinically significant coronary artery disease
4. Any procedure, condition or cardiac anatomy that may impact or compromise the pericardial space (e.g. prior mitral valve surgery, CABG, epicardial pacing leads, pericarditis, or other procedure involving pericardial access)
5. Percutaneous coronary intervention, acute coronary syndrome (e.g. STEMI or non-STEMI myocardial infarction, unstable angina) or clinically significant cardiac events (e.g hypotension, syncope, arrhythmias, embolism, heart failure exacerbation or any hospitalization) within 30 days of enrollment
6. Thoracic or cardiac surgery contraindication (e.g., acute respiratory distress, endocarditis, myocarditis, pericarditis)
7. Significant structural abnormality of the mitral valve (e.g. flail leaflets, ruptured or elongated chordae, prolapsed valve, perforated valve leaflets, significant calcification in the annulus, or calcification in the leaflets that restricts motion)
8. Severe symptomatic carotid stenosis
9. Severe or sustained pulmonary hypertension, defined by resting pulmonary artery systolic (PAS) pressure greater than or equal to 70 mm Hg
10. Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction
11. Hypotension (systolic pressure <90mm Hg)
12. Hypertrophic cardiomyopathy, restrictive cardiomyopathy, or any other structural heart disease causing heart failure other than dilated cardiomyopathy
13. UNOS status 1 heart transplantation
14. Creatinine > 2.5 mg/dL (221 µmol/L) and/or renal failure requiring dialysis
15. Active systemic infection or bleeding
16. Autoimmune disorders and/or the use of immune suppression therapy
17. Females who are pregnant (as documented by HCG beta pregnancy test in females of child-bearing age) or lactating
18. Currently enrolled in another investigational drug or device study;Intra-operative Exclusion Criteria: Subjects will be excluded if they meet any of the following criteria:
1. Subjects with heart size outside of the offered VenTouch System size range
2. Significant structural abnormality of the mitral valve (e.g. flail leaflets, ruptured or elongated chordae, prolapsed valve, perforated valve leaflets, significant calcification in the annulus, or calcification in the leaflets that restricts motion)
3. Signs/indications of ischemia
4. Intra-operative coronary angiography demonstrates that there is compression of the coronary arteries or reduction in coronary blood flow due to the VenTouch implant

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	5
Type:	Anticipated

Medical products/devices used

Generic name:	VenTouch System
Registration:	No

Ethics review

Approved WMO

Date:	05-10-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT02671799
CCMO	NL54157.058.15