A multi-center study of the safety and efficacy of the percutaneous transvenous mitral annuloplasty system to reduce mitral valve regurgitation in patients with heart failure.

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

Summary

ID

NL-OMON33252

Source
ToetsingOnline

Brief title
Ptolemy-2

Condition

- Cardiac valve disorders

Synonym
mitral regurgitation, mitral valve leakage

Research involving
Human

Sponsors and support

Primary sponsor: Viacor Inc.
Source(s) of monetary or material Support: Medische Hulpmiddleen industrie,Viacor Inc.

Intervention

Keyword: Heart failure, Mitral valve regurgitation, Percutaneous transvenous mitral annuloplasty (PTMA)

Outcome measures

Primary outcome

1. Safety - The primary safety endpoint is the Freedom from MACE rate defined as the % of implanted patients who remain free from device or procedure related major adverse events (death, MI, emergent cardiac surgery, and stroke). Safety endpoint success will be considered 90% freedom from procedure or device-related MACE at 30 days post procedure (or hospital discharge which ever is longer) for all enrolled patients as assessed by an independent medical monitor.

2. Efficacy - The primary efficacy endpoint is the quantitative MR reduction at 6 months. Efficacy success of the Viacor PTMA study is defined as a minimum 1.0 point MR improvement score in 50% of implanted patients at 6 months. MR improvement score is defined as a continuous variable composite of quantitative MR measures (see page 10).

Patients from whom the implant is removed prior to the 6 month follow-up will be excluded from analysis of efficacy endpoints.

Secondary outcome

1. Safety - to assess the safety of the PTMA* implant device and procedure as measured by:

a. The % of enrolled patients who experience procedure or device-related in-hospital complications.

b. The % of implanted patients who remain free from procedure or device-related adverse events at 30 days and 6 months.

c. The % of implanted patients who remain free from major adverse events (death, MI, emergent cardiac surgery, and stroke) at 6 months.

d. The % of implanted patients with freedom from device failure or migration at 1 year.

2. Efficacy

a. Technical procedure success: the % of implanted patients who maintain a reduction of mitral annulus A/P dimension of >= 15% at 30 days and 6 months.

b. Technical procedure success: the % of implanted patients who maintain a sustained reduction in MR at 30 days and 6 months. Implanted patients will be classified as hemodynamic responders if they exhibit a reduction equal to or greater than 10 mL of regurgitant volume, or 10% regurgitant fraction, or 0.1 cm2 of EROA.

c.. Technical procedure success: the % of implanted patients who maintain a sustained decrease in LVEDV and LVESV or LVEDD and LVESD at 6 months.

d. Clinical Status: the % of implanted patients who exhibit a greater than 5 point reduction (improvement) in Minnesota Living with Heart Failure score from study baseline to 30 days and 6 months.

e. Clinical Status: the % of implanted patients who exhibit a greater than 25 meter improvement in 6 minute walk test from study baseline to 30 days and 6

months.

Study description

Background summary

The Viacor® Percutaneous Transvenous Mitral Annuloplasty (PTMA*) system comprises a sterile implantable cardiac device and associated custom accessories to assist implantation. The PTMA system is intended to treat functional mitral regurgitation (MR) in a heart failure patient by a less invasive method than surgical annuloplasty with greater relief of symptoms than medical management alone.

Study objective

Functional mitral regurgitation is associated with an adverse prognosis in the heart failure patient. The objective of this study is to evaluate whether PTMA is effective in reducing mitral regurgitation in heart failure patients and whether this reduction is associated with a moderation in the adverse progression of heart failure symptoms.

Study design

This study is an open-label, single-arm study of the safety and efficacy of the Viacor PTMA* system

Intervention

Implantation of the PTMA device

Study burden and risks

It is important to note that the risks associated with PTMA are currently not fully understood. Implanting the device resembles the implantation of pacemaker electrodes. Based on this, it is estimated that the chance of risks associated with the placement of the device is less than 1% to 2% for perforation, trombusvorming, tamponade, pneumothorax and myocardinfract and 1% in terms of infections. Some of these risks can be disability or death.

Moreover, there is a risk that the mitral valve regurgitation can return over time. In this case the implant can be modified or removed. If PTMA is no longer effective in reducing the mitral valve regurgitation, options are discussed with the patient. It should be noted that the risk of death during an open

heart surgery to repair mitralisklep to 2% to 8%.

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 has moderate functional MR: regurgitant orifice area >/= 0.20cm2 or regurgitant volume >/= 30 mL/beat or regurgitant fraction >/= 30%.
2. Symptomatic heart failure NYHA Class II to IV
3. LV dysfunction (25% < LVEF < 50% by echocardiography)
4. Age >/= 50 Years.
5. Patient has signed the informed consent agreement.

Exclusion criteria

Exclusion Criteria
1. Mitral regurgitation of organic origin such as: degenerative disease (prolapse), rheumatic disease (commissural fusion, shortening and thickening of the subvalvular apparatus), endocarditis, flail segments, congenital mitral disease, significant annular calcification, significant pathology of the chords.
2. Severe mitral leaflet tethering.
3. Valvular apparatus cannot be visualized by 2D transthoracic echo. Valvular regurgitation cannot be quantified by 2D echo PISA or Doppler techniques.
4. Serious allergy to intravenous contrast agents or serious renal dysfunction (glomerular filtration rate less than 30 ccs/minute, as calculated by the Cockroft-Gult equation), or otherwise major contra-indication for contrast angiography.
5. History of myocardial infarct (MI) within 60 days prior to study procedure.
6. History of PCI within 60 days prior to study procedure.
7. Patient is not capable of walking 100 meters in 6 minutes.
8. Patient cannot complete the QOL survey with a meaningful score.
9. Indication of left-dominant coronary circulation with angiography.
10. Significant (>30% occluded) Left Main stenoses or proximal circumflex stents unless affected area has been by-passed surgically.
11. Indication of non-patent CSO or discontinuous CS-GCV-AIV with venography, MRI, or cardiac CT.
12. Planned CABG or mitral valve surgery or planned biventricular pacemaker requiring placement of leads in the coronary sinus.
13. Existing bi-ventricular pacemaker with leads in the coronary sinus or its tributaries. Presence of instrumentation that in the clinician*s judgment will either impede safe placement of the study device, and/or will be dislodged or will malfunction as a result of placement of the study device.
14. Existing prosthetic mitral valve implant or annuloplasty ring.
15. Acute systemic infection (including septicemia or leukocytosis greater than 15,000/dL), active infections including endocarditis or fever greater than 38.5° C.
16. Chronic steroid use or intravenous steroid use within the past 60 days.
17. Major organ system disease such as hepatic dysfunction including cirrhosis, esophageal varices, or severe chronic obstructive pulmonary disease (COPD), at least GOLD stage III or greater.
18. History of major thrombo-embolic event within past three months (i.e. cerebral-vascular event, stroke, pulmonary or arterial embolism).
19. Existing bleeding diathesis: elevated PT INR (>1.5), elevated aPTT, platelet count <100,000, unless this can be adjusted with a change to existing medication.
20. Patient refuses blood products.
21. Patient has a significant gastrointestinal (GI) bleed within the past three months.
22. Uncontrolled thyroid disease.
23. Severe autoimmune system disease or history of hypercoagulable state.
24. Participation in a drug or device trial if such participation would impact the PTMA* study and follow-up.
25. Life expectancy of less than 1 year or any condition which, based on the investigator*s

clinical judgment, would prevent the patient from completing required study procedures, including follow-up.
26. Female patients of childbearing potential if lactating, or with a positive pregnancy test within 7 days of planned procedure.
27. Patient requires emergency surgery, or is clinically unstable due to such causes as hemodynamic instability or significant active and uncontrolled angina.
28. Known inability to comply with baseline and follow-up requirements for imaging studies.
29. Known inability to comprehend the required consent documentation.

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):	28-10-2009
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	Percutaneous transvenous mitral annuloplasty
Registration:	No

Ethics review

Approved WMO

Date:	23-07-2009
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	NL27572.078.09