Mitral Adjustable Annuloplasty Ring Feasibility and Safety Study

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Establish the technical feasibility and safety of implantation of the investigational device, adjustment of the investigational device post-implantation and the ability of the investigational device to reduce mitral valve regurgitation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON31130

Source
ToetsingOnline

Brief title
MARRS

Condition

- Congenital cardiac disorders
- Cardiac therapeutic procedures

Synonym
MR

Research involving
Human

Sponsors and support

Primary sponsor: MitralSolutions, Inc.
Source(s) of monetary or material Support: MitralSolutions;Inc.

Intervention

Keyword: Mitral Adjustable Annuloplasty Ring

Outcome measures

Primary outcome

Safety: Freedom from device related major adverse events (MAE) at 30 days.

Performance: Technical success rate of implantation of the investigational device.

Secondary outcome

Performance:

Ability to adjust the investigational device post-ring implantation after the patient has been weaned from CPB

MR reduction post-procedure at post-operative hospital discharge, 30 days and at 90 days

Study description

Background summary

Multicenter study to assess the safety and performance of the device for the purpose of obtaining the CE Mark.

Study objective

Establish the technical feasibility and safety of implantation of the investigational device, adjustment of the investigational device post-implantation and the ability of the investigational device to reduce

mitral valve regurgitation.

Study design

single arm, prospective

Intervention

Surgicall implanted device.

Study burden and risks

Risks:
*Death
*Myocardial infarction
*Stroke/ transient ischemic attack
*Hemolysis
*Heart block
*Perforation or damage of vessels, myocardium or valvular structures
*Pericardial effusion/cardiac tamponade
*Haematoma
*Blood loss requiring transfusion
*Infection including endocarditis and septicaemia
*Arrhythmia
*Air embolus
*Thromboembolism
*Fever
*Hypertension/hypotension
*Allergic dye reaction
*Anaesthesia reactions

In addition to the risks listed above, the potential risks specifically associated with the mitral valve annuloplasty procedures include, but may not be limited to, the following:
*Device dehiscence resulting in residual mitral regurgitation
*Systolic Anterior Motion
*Left Ventricular Outflow Tract Obstruction
*Residual or recurrent valvular insufficiency requiring intervention
*Coronary occlusion of the left circumflex artery (LCX) from suturing the device to the valve resulting in myocardial infarction (MI)
*Annular ventricular dehiscence leading to ventricular rupture

In addition to the risks associated to the annuloplasty procedure in general, risks associated specifically to the MitralSolutions Adjustable annuloplasty system include, but may not be limited to the following:
*Unsuccessful adjustment of the ring size

*Suture distortion or pull-out due to device adjustment placing stress on suture points
*Tissue damage from insertion and removal of the adjustment tool

Benefits:
The proposed product and surgical procedure are aimed at benefiting the patients physically as well as emotionally. Although there are no guaranteed benefits from participation in this study, it is possible that treatment with the MitralSolutions Adjustable Annuloplasty Ring will provide the potential for fewer clinical complications resulting from inadequate sizing of the annulus associated with standard annuloplasty rings on the market.

Mitral valve repair using MitralSolutions annuloplasty system emulates the same technique used by conventional non-adjustable annuloplasty rings. The reduction of the septal-lateral annular dimension is the primary mechanism used by current annuloplasty rings/systems whose focus is treating ischemic or functional mitral regurgitation, however, currently available rings are not adjustable and require the availability of multiple ring sizes. Unlike currently marketed rings which do not allow for adjustment after implant or weaning from CPB, the MitralSolutions annuloplasty system offers the clinician the opportunity to make adjustments to minimize or eliminate residual regurgitation (or possibly, systolic anterior motion of the mitral valve) after weaning from CPB using a titanium mechanical gear system that reduces the septal-lateral (S-L) dimension of the mitral valve with precision. With conventional annuloplasty rings, if moderate residual mitral regurgitation is present after implant, a re-repair requires the patient to be placed back on CPB. The annuloplasty ring is then removed and replaced with a different size or configuration ring; often, the native mitral valve is replaced with a prosthetic valve.

The adjustability feature of the MitralSolutions annuloplasty system ring may reduce the number of patients leaving the operating room with mild to moderate residual mitral regurgitation after mitral valve repair, since further reduction of the S-L annular dimension can be made under TEE guidance after weaning from CPB. The MitralSolutions annuloplasty system may offer a potentially safer procedure compared to conventional mitral annuloplasty techniques by reducing the likelihood that a patient would need a re-repair or replacement of the valve due to residual mitral regurgitation stemming from initial inaccurate sizing and fit of an annuloplasty ring to the mitral valve.

Contacts

Public
MitralSolutions, Inc.

1700 East Las Olas Blvd., Suite 203
Fort Lauderdale, FL 33301
United States
Scientific
MitralSolutions, Inc.

1700 East Las Olas Blvd., Suite 203
Fort Lauderdale, FL 33301
United States

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Males or females aged *18 to *75 years. ;Patients with *Grade 2+ mitral regurgitation by pre-operative Trans-Thoracic Echo assessment.;Candidate for cardiopulmonary bypass. ;A Left Ventricular Ejection Fraction *40%. ;Able and willing to comply with all study requirements, including the required study follow-up visits. ;Able and willing to give consent and follow study instructions. ;Female patients of childbearing potential (not surgically sterilized or more than one year postmenopausal), with a negative pregnancy test (serum beta-hCG) within 24 hours prior to mitral valve surgery.

Exclusion criteria

Any previous cardiac surgery.;Any interventional cardiology procedure within six months prior to study to include all patients that have had a drug eluting stent (DES) implanted within 6 months. ;Evidence of an acute Myocardial Infarction (MI) within 7 days of the intended treatment with the investigational device.;Prior mitral valve surgery or valvuloplasty or currently implanted prosthetic valve.
Restricted mobility of the mitral apparatus that results in a valvular area less than 3.0 cm2.;Recent or evolving bacterial endocarditis or patients under current antibiotic

therapy.;Patients with ICD*s.;Any angiographic or clinical evidence that the investigator feels would place the patient at increased risk with the placement of the device or concurrent medical condition with a life expectancy of less than 12 months.;Patients who are immunocompromised or with autoimmune diseases.;Patients suffering from renal insufficiency (Creatinine >2.5 mg/dL) or patients with chronic renal failure undergoing dialysis.;Co-morbid conditions that place the subject at an unacceptable surgical risk (e.g. sever chronic obstructive pulmonary disease, hepatic failure, immunosuppressive abnormalities, haematological abnormalities).;Significant mitral annular calcification.;Use of Coumadin, IIbIIIa inhibitors, Clopidigrel (Plavix) or other anti-coagulants within (5) five days prior to surgery. ;Participation in any study involving an investigational drug or device within the past month, or ongoing participation in a study with an investigational device. Intolerance or hypersensitivity to anaesthetics.;Patients in whom transesophageal echo/Doppler is contraindicated.;History of bleeding diathesis or coagulopathy.;History of stroke within the prior 6 months.;Subjects to undergo concomitant cardiac surgical repair or replacement other than CABG (3 vessels or less) and mitral annuloplasty. Excluded concomitant procedures are: aortic valve replacement, tricuspid repair or replacement, left ventricular remodelling surgery and congenital repair.;Patients with a Euroscore >10.

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):	18-10-2007
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	MitralSolutions Adjustable Annuloplasty Ring
Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
Other	DE/CA84/73-KL-19-07
CCMO	NL18147.058.07