DYANA Study - Dynamic Annuloplasty System with Activation for the Treatment of Mitral Regurgitation

Published: 19-05-2009
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To evaluate and compare complication and mortality rates tocurrent rates available for repairs with commercially availableannuloplasty rings. (0, 0+)

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

Summary

ID

NL-OMON33949

Source
ToetsingOnline

Brief title
DYANA Study

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
Heartvalve leakage, Mitral valve regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: MiCardia Corporation, Jody L. Errandi M.S., Director of Clinical
Source(s) of monetary or material Support: MiCardia Corporation

Intervention

Keyword: Annulus, Mitral valve, Regurgitation, Repair

Outcome measures

Primary outcome

The primary safety endpoint is the occurrence of; death, endocarditis, ring dehiscence, systolic anterior motion (SAM), embolic event, pulmonary edema, heart block, arrhythmia, hemolysis, and myocardial infarction (MI) at 30 days post-procedure.

The primary efficacy endpoint is ability to reduce mitral regurgitation to less than 2+ immediately following surgical implantation of the annuloplasty device.

Secondary outcome

The secondary safety endpoint is the occurrence of; death, endocarditis, ring dehiscence, systolic anterior motion (SAM), embolic event, pulmonary edema, heart block, arrhythmia, hemolysis, and myocardial infarction (MI) at 6 months post-procedure.

The secondary efficacy endpoint is the ability to further reduce residual regurgitation following annuloplasty ring implantation and /or to enhance coaptation distance using intra-operative activation of the device.

Study description

Background summary

Surgically placed annuloplasty ring for the treatment of mitral regurgitation (MR) with an intra-operative shape change option for additional optimization.
To assess the safety and efficacy of the MiCardia Dynamic Annuloplasty System for the treatment of mitral regurgitation with optional intraoperative activation and optimization.
The Dyana ring will be used for the first time in humans.

Study objective

To evaluate and compare complication and mortality rates to current rates available for repairs with commercially available annuloplasty rings. (0, 0+)

Study design

Single arm, multi-center, prospective study

Intervention

Surgically placed annuloplasty Nitinol ring for the treatment of mitral regurgitation (MR) with an intra-operative shape change option for additional optimization.
Shape change will be achieved by RF energy.

Study burden and risks

ADDITIONAL RISK WITH THE USE OF INTRA-OPERATIVE ACTIVATION
Risks of the Intra-Operative Wire Placement
· Perforation/tamponade
· Pericardial Effusion
· System damage
Risks of the Intra-Operative Wire Activation
· Possibility of Heart arrhythmia
· Possibility of tissue damage with the RF energy
· Thrombosis
· Risk of bleeding of left atrial incision
· Ring damage
· Ring dehiscence
Risks of the Reshaped Dynamic Annuloplasty Ring
· Possibility of worsening MR
· Possibility of tissue damage due to tension
· Possibility of suture stitch damage

Benefits
The use of The MiCardia Dynamic Annuloplasty Ring System allows for conventional surgical
mitral valve repair with the optional feature of off-pump real-time ring shape adjustment. The
direct benefit to the patient is the ability of the surgeon to review the echocardiographic data post
surgical implant and allow for ring shape changes to reduce any residual MR that may be present
and/or to optimize leaflet coaptation. Both adjustment options are to improve the initial surgical
outcome, which is expected to minimize the likelihood of a second, invasive by-pass surgery.

Contacts

Public
MiCardia Corporation, Jody L. Errandi M.S., Director of Clinical

30 Hughes, Suite 206,
Irvine, CA USA 92618
US
Scientific
MiCardia Corporation, Jody L. Errandi M.S., Director of Clinical

30 Hughes, Suite 206,
Irvine, CA USA 92618
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.This patient requires mitral valve repair with or without concomitant procedures such as coronary artery bypass or another valve reconstruction or replacement.
2.This patient has been diagnosed with a diseased natural valve, based on echocardiography and is a candidate for mitral valve repair.
3.This patient is in satisfactory condition, based on the physical exam and investigator's experience, to be an average or better operative risk. (i.e., likely to survive one year postoperatively)

Exclusion criteria

1. This patient is less than eighteen (18) years of age.
2. This patient has a non-cardiac major or progressive disease, which in the investigators experience produces an unacceptable increased risk to the patient, or results in a life expectancy of less than twelve months.
3. Patient who has heavily calcified annulus or leaflets.
4. reoperation

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):	12-08-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Adjustable Mitral Annuloplasty Ring System

Registration:	No

Ethics review

Approved WMO Date:	19-05-2009
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	NL26230.078.09