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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24536

Source
Nationaal Trial Register

Brief title
DYANA Study

Health condition

Mitral Regurgitation
Mitral Insufficiency
Annuloplasty Ring
Mitral Valve Dysfunction

Mitralis Regurgitatie
Mitralis Insufficientie
Annuloplastiek Ring
Mitraal Klep Dysfunctioneren

Sponsors and support

Primary sponsor: MiCardia Corporation
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Intervention

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, or myocardial infarction (MI) at 30 days post-procedure.

The primary efficacy endpoint is the 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 or 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

Title:

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

Design:

Single arm, multi-center, prospective study.

Brief Description:

Surgically placed annuloplasty ring for the treatment of mitral regurgitation (MR) with an intra-operative shape change option for additional optimization.

Purpose:

To assess the safety and efficacy of the MiCardia Dynamic Annuloplasty System for the treatment of mitral regurgitation with optional intraoperative activation and optimization.

Enrollment:

A cohort of up to one hundred thirty (130) patients will be considered for this study. Approximately 30 patients are possible at each site, but sites are not limited to any number. Once total enrollment reaches 130, enrollment will stop.

Clinical Sites:

Up to fifteen (15) sites in Europe and Canada.

Patient Population:

Patients with functional or degenerative mitral regurgitation amenable to surgical annuloplasty therapy.

Study Aim:

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

Safety Endpoints:

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

To assess the safety and efficacy of the MiCardia Dynamic Annuloplasty System for the treatment of mitral regurgitation with optional intraoperative activation and optimization.

Study design

Screening, baseline, procedure, discharge, PO 30 days, 6 months PO.

Intervention

Subject is screened and given Baseline assessments conform daily rourine for Open Heart Surgery. Baseline TTE will be done.

Procedure: patient is receives the DYANA ring during Open Heart Surgery. Pre and post implant TEE will be done.

Discharge Routine Interventions plus a TTE will be done.

On 30 days PO and 6 months PO the routine interventions will be done plus a TTE.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient requires mitral valve repair with or without concomitant procedures such as coronary artery bypass or another valve reconstruction or replacement;

2. patient has been diagnosed with a diseased natural valve, based on echocardiography and is a candidate for mitral valve repair;

3. 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);

4. patient is geographically stable and willing to return to the implant center for follow-up visits;

5. Documentation signed and dated confirming that this patient has been adequately informed of his/her participation in the clinical study, and of what will be required of him/her, in order to comply with the protocol.

Exclusion criteria

1. Patient is less than eighteen (18) years of age;

2. 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 has an ejection fraction < 30%;

4. patient has a heavily calcified annulus or leaflets;

5. patient presents with active endocarditis or has had active endocarditis in the last 3 months;

6. patient is pregnant (urine HCG test result positive) or lactating;

7. patient is an intravenous drug abuser or alcohol abuser;

8. patient has a previously implanted prosthetic mitral valve or annuloplasty ring/band;

9. patient requires mitral valve replacement;

10. patient has a creatinine level > 2.0 mg/dl;

11. patient has had congestive heart failure within the past 6 months requiring surgical treatment;

12. patient has had a coronary artery ischemic event within the past 6 months requiring surgical treatment;

13. patient has a known life threatening, non-cardiac disease that will limit the patients life expectancy to less than one year;

14. patient is unable to take antiaggregant medications;

15. patient has a known untreatable allergy to contrast media or nickel;

16. patient has had a cerebral vascular event within the past 6 months;

17. patient is a prisoner (U.S.A. Only);

18. patient is participating in concomitant research studies of investigational products;

19. patient will not agree to return to the implant center for the required number of follow-up.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	15
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1541
NTR-old	NTR1612
Other	: THCHOZ-2008-013
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results