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

Gepubliceerd: 02-01-2009 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24536

Bron
NTR

Verkorte titel
DYANA Study

Aandoening

Mitral Regurgitation
Mitral Insufficiency
Annuloplasty Ring
Mitral Valve Dysfunction

Mitralis Regurgitatie
Mitralis Insufficientie
Annuloplastiek Ring
Mitraal Klep Dysfunctioneren

Ondersteuning

Primaire sponsor: MiCardia Corporation
Primary (U.S.) Contact:
Jody L. Errandi M.S. CORMEDICS

Director of Clinical Research
MiCardia, Incorporated
30 Hughes, Suite 206
Irvine, CA 92618
U.S.A.
Phone: +1.949.951.4888
Fax: +1.949.756.4525
Email: jerrandi@micardia.com
Overige ondersteuning: MiCardia Corporation
Primary (U.S.) Contact:
Jody L. Errandi M.S. CORMEDICS
Director of Clinical Research
MiCardia, Incorporated
30 Hughes, Suite 206
Irvine, CA 92618
U.S.A.
Phone: +1.949.951.4888
Fax: +1.949.756.4525
Email: jerrandi@micardia.com

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Erasmus University Medical Center
PO Box 2040

L. Duininck
Dept. Cardio-Thoracic Surgery, Bd-563
Erasmus University Medical Center
Rotterdam
Rotterdam 3000 CA
The Netherlands
+31 10 70 32 150

Wetenschappelijk

Erasmus University Medical Center
PO Box 2040

L. Duininck
Dept. Cardio-Thoracic Surgery, Bd-563
Erasmus University Medical Center
Rotterdam
Rotterdam 3000 CA
The Netherlands
+31 10 70 32 150

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1541
NTR-old	NTR1612
Ander register	: THCHOZ-2008-013
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten