A Study to Evaluate the Feasibility and Safety of the Millipede Transcatheter Annuloplasty Ring System in Patients with Functional Mitral Regurgitation

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The objective of this study is to evaluate the feasibility and safety of the Millipede Transcatheter Annuloplasty Ring System in patients with functional mitral regurgitation.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON50054

Source
ToetsingOnline

Brief title
Millipede Feasibility Study

Condition

- Cardiac valve disorders

Synonym
repair of the mitral valve - a backflow of blood within the heart due to the failure of the mitral valve to close properly

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Cooperation International

Source(s) of monetary or material Support: Industry;Boston Scientific Corporation

Intervention

Keyword: Millipede System, Mitral Regurgitation Treatment

Outcome measures

Primary outcome

The primary safety endpoint, measured in-hospital, is technical success:

defined as successful delivery of the device in the correct anatomical position

and withdrawal of the delivery system without conversion to surgery or

in-hospital mortality.

Secondary outcome

Additional endpoints include clinical measures, functional measures, imaging

parameters and device performance. For detailed list of endpoints, please refer

to section 6.2 of the Protocol

Study description

Background summary

The Millipede Annuloplasty Ring System is a novel transcatheter, fully adjustable, complete annuloplasty repair device for the treatment of mitral regurgitation. The device is designed to mimic a widely used surgical intervention with a percutaneous therapy. As such, it potentially offers a less invasive and safer treatment for mitral regurgitation in comparison to surgery.

Millipede conducted a series of acute and chronic animal studies to evaluate the feasibility and safety of the Millipede System in support of initiating early clinical studies.

These clinical studies demonstrated that the Millipede device can be safely implanted in humans with a subsequent reduction in the mitral regurgitation grade. The Millipede Transcatheter Annuloplasty Ring System IB contains a

detailed summary of these clinical studies.

Study objective

The objective of this study is to evaluate the feasibility and safety of the Millipede Transcatheter Annuloplasty Ring System in patients with functional mitral regurgitation.

Study design

The Millipede Feasibility Study is a prospective, open-label, single-arm study to assess the safety and feasibility of the Millipede Transcatheter Annuloplasty Ring System in patients with functional mitral regurgitation.

Intervention

Not applicable

Study burden and risks

Risk associated with Millipede system are listed in the Instructions For Use, Investigator*s Brochure, Protocol and Informed Consent Form.

Additional risks may exist. Risks can be minimized through compliance with the protocol, performing procedures in the appropriate hospital environment, adherence to subject selection criteria, close monitoring of the subject*s physiologic status during research procedures and/or follow-ups and by promptly supplying BSC with all pertinent information required by this protocol.

Data will be monitored as they are submitted to sponsor. Qualified employees at sponsor, or a designee under contract, will conduct monitoring visits at the initiation of the study and at interim intervals described in the monitoring plan throughout the course of the study to evaluate protocol compliance and determine if there are any issues that could affect the safety or welfare of any subject in the study.

Transcatheter mitral valve repair (TMVr) may offer certain advantages when compared to surgical repair of the mitral valve. Known benefits of a minimally invasive procedure and reduced risk related to open heart surgery may include shorter overall hospital stay, reduced blood loss and more rapid recovery

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

IC1: Subject is 18 Years of age or older
IC2: Subject (or legal guardian) understands the trial requirements and the treatment procedures and provides informed consent before any trial -specific tests or procedures are performed
IC3: Subject has moderate to severe (3+) or severe (4+) functional mitral regurgitation(a) confirmed by the echocardiography core lab.
IC4: Subject is symptomatic (NYHA Class II-IV) despite guidelines directed medical therapy, including CRT if indicated
IC5. The local site heart team concurs that mitral valve surgery will not be offered as a first-line treatment option
IC6. Subject is a candidate for annuloplasty based on the criteria below as assessed by the investigative site (and confirmed by the Case Review Committee):
• LVEF >= 25%
• LVEDD <= 65 mm
• Coaptation distance (i.e. tenting height) < 10 mm

• Absence of posterior wall aneurysm

(a): Assessment per the American Society of Echocardiography mitral regurgitation grading criteria [24, 25]
Abbreviations: CRT=cardiac resynchronization therapy; LVEDD=left ventricular end diastolic diameter; LVEF=left ventricular ejection fraction; NYHA=New York Heart Association

Exclusion criteria

EC1. Subject has severe calcification of the mitral annulus or leaflets, other anatomic features that makes the patient unsuitable for annuloplasty with the Millipede System in the judgment of the treating physician or subject does not have suitable mitral annular diameter (determined by computed tomography) as per the Instructions For Use).
EC2. Transfemoral venous and transseptal access determined not to be feasible
EC3. Subject is on the waiting list for a transplant or has had a prior heart transplant
EC4. Subject has had a cerebrovascular accident (CVA) or transient ischemic attack (TIA) within 30 days prior to study enrollment
EC5. Subject has had any percutaneous coronary, carotid, or other endovascular intervention within 30 days prior to study enrollment
EC6. Subject has had carotid surgery within 30 days prior to study enrollment
EC7. Subject has had any open coronary or vascular surgery (other than carotid surgery) within 3 months prior to study enrollment
EC8. Subject has had a cardiac resynchronization therapy (CRT) device implantation within 3 months prior to study enrollment
EC9. Subject has untreated clinically significant coronary artery disease requiring revascularization
EC10. Any planned cardiac surgery within the next 12 months
EC11. Need for emergent or urgent surgery for any reason
EC12. Subject has severe aortic valve stenosis and/or aortic valve regurgitation
EC13. Subject has physical evidence of right-sided congestive heart failure (CHF) plus echocardiographic evidence of moderate or severe right ventricular dysfunction and/or severe tricuspid valve regurgitation
EC14. Subject has the presence of prosthetic heart valve in any position
EC15. Subject has renal insufficiency (eGFR <20 mL/min) and is not on dialysis
EC16. Subject has a life expectancy less than 12 months
EC17. Subjects in whom trans-esophageal ECHO/Doppler is contraindicated or in which mitral regurgitation is not measurable by transthoracic echocardiogram (TTE)
EC18: Subject has a prior history of atrial septal defect (ASD) closure or patent foramen ovale (PFO) closure.
EC19: Subject has a fixed pulmonary artery systolic pressure >70 mmHg.

EC20: Subject has known hypersensitivity or contraindication to protocol required procedural or post procedural medication (e.g., anticoagulation therapy) or hypersensitivity to nickel or titanium
EC21. Subject has known hypersensitivity to contrast that cannot be adequately premedicated
EC22. Female subject who is breast feeding or pregnant or planning to become pregnant within the study period.
EC23. Subject is participating in another investigational drug or device study that has not reached its primary endpoint or subject intends to participate in another investigational device clinical trial within 12 months after index procedure.
EC24. Subject has a history of endocarditis within 6 months of index procedure or evidence of an active systemic infection or sepsis.
EC25. Subject has oxygen-dependent chronic obstructive pulmonary disease.
EC26. Subject has documented severe liver disease.
EC27. Subject has Hgb <8 g/dL, platelet count <50,000 cells/mm3 or >700,000 cells/mm3, or white blood cell count <1,000 cells/mm3.
EC28. Subject has any evidence of intracardiac thrombus.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Millipede System
Registration:	No

Ethics review

Approved WMO Date:	24-09-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-11-2021
Application type:	Amendment
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
ClinicalTrials.gov	NCT04147884
CCMO	NL74260.078.20