Early Transcatheter Mitral Valve Repair after Myocardial Infarction (EMCAMI)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57128

Source
ToetsingOnline

Brief title
EMCAMI

Condition

- Cardiac valve disorders

Synonym
Leaking heart valve

Research involving
Human

Sponsors and support

Primary sponsor: Meditrial Europe Ltd.
Source(s) of monetary or material Support: Er zal geen enkele vorm van geldstroom zijn

Intervention

Keyword: Mitral Valve Repair, Myocardial Infarction

Outcome measures

Primary outcome

Primary endpoint [Time Frame: 12 months]:

Composite of

1. All-cause death

2. Cumulative HF hospitalizations

Secondary outcome

Secondary endpoints [Time Frame: 24 months]:

1. Quality of Life (QOL) assessed using KCCQ-12 (Appendix I)

2. New York Heart Association (NYHA) functional class (Appendix II)

3. LV remodeling parameters (e.g., LV size, LV function, pulmonary pressures,

RV function)

4. Mitral Regurgitation (MR) severity

5. Myocardial infarction (MI)

6. Stroke

7. Renal complication with requirement for dialysis

8. Major vascular complications

9. Major and/or life-threatening bleeding

10. Need for mitral valve surgery

In addition, all heart failure (HF) events according to latest working group

definition will be recorded in the CRF for additional analyses.

Study description

Background summary

Mitral valve regurgitation, also known as mitral valve insufficiency, is a condition where the mitral valve in the heart does not close properly. This allows blood to flow back from one of the two lower chambers of the heart (left ventricle) to the upper chamber on the left side of the heart (left atrium), whereas blood should only flow in one direction, from the left atrium to the left ventricle. Left untreated, mitral valve insufficiency can damage the heart. To prevent this, medication is prescribed, and depending on the progression, open-heart surgery may be considered (only if the patient's risk is not too high).

In recent years, a new technique has been developed and widely used in daily clinical practice to repair the mitral valve in certain specific cases using a catheter, without the need for open-heart surgery. This method, also known as transcatheter Edge-to-Edge Repair (TEER), is particularly suitable for patients for whom surgery may pose risks and has already been successfully applied in many situations. The procedure involves making a small incision in the femoral vein (known as transfemoral access, i.e., "via the right or left femoral vein"), while the patient is under anesthesia. The mitral valve placement system (a catheter) passes through the femoral vein and reaches the heart without opening the chest or stopping the heart.

We are conducting this research to evaluate the best treatment method in this situation: using the standard treatment method with medication alone, or combining the standard treatment method with medication with repair using a non-surgical transcatheter technique (TEER method). In this technique, one or more clips (MitraClip) are used to grasp and connect the mitral valve leaflets, reducing mitral valve insufficiency. The evaluation conducted during this research investigates the different treatment methods, all of which are already applied in contemporary practice.

Study objective

The main objective of the study is to investigate whether early repair (within 60 days after a heart attack) of the mitral valve, using a non-surgical transcatheter technique (TEER) in combination with the standard medical therapy required for the heart condition, reduces the risk of death and long-term hospitalizations due to heart problems in the year following the procedure. The study will evaluate, through a two-year follow-up, how this treatment affects your quality of life and the functionality of your heart.

All devices, medications, and procedures used in this study are commercially

approved and constitute standard care.

Study design

Prospective, multicenter, randomized, open-label, comparative effectiveness clinical trial for the treatment of clinically significant functional mitral regurgitation within 60 days after acute myocardial infarction, who are treated per Standard Medical Therapy per Institution Guidelines (SMTIG) and who have been determined by the site's local Heart Team as inappropriate or too high risk for mitral valve surgery.
Eligible subjects will be randomized in a 1:1 ratio to the MitraClip device (interventional group) or to the Standard Medical Therapy per Institution Guidelines alone (control group).

Study treatment starts after randomization, follow-up will start after initial study treatment was done (Time of TEER for the interventional group or 1 months after randomization for the control group). Medical therapy will be adjusted to patient needs during the whole follow-up period, treatment choices will be left at the discretion of the treating physicians. This means that the treating physician can decide to switch participants from one group to the other.

Intervention

In the study, the repair of the mitral valve using a catheter is considered the intervention. However, this is already a standard treatment and is applied daily in the hospital.

A brief explanation:
In recent years, a new technique has been developed that is widely used in daily clinical practice: repair of the mitral valve using a catheter. This method is also known as the "Transcatheter Edge-to-Edge Repair (TEER)." It is a non-surgical transcatheter technique where one or more clips (MitraClip) are used to grasp and connect the mitral valve leaflets, thereby reducing mitral valve insufficiency. The procedure is performed by making a small incision in the femoral vein (so-called transfemoral access, i.e., "via the right or left femoral vein"), while the patient is under anesthesia. The mitral valve placement system (a catheter) goes through the femoral vein and reaches the heart without opening the chest or stopping the heart.

Study burden and risks

Treatment as part of this study is identical to treatment outside of this study. Participation in the study will not impact the procedure or use of the device in any way.

Potential risks associated with the TEER procedure are well known and accepted.

The potential complications listed in the IFU of the study device, would be explained to the patients regardless of study participation.

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

1. Patients with symptomatic moderate to severe or severe MR that develops after acute myocardial infarction (AMI)
2. Age > 18 years
3. Clinical presentation of AMR must fulfill one of the following scenarios, as proposed by Shuvy et al. [1]:
a. TYPE 2: Refractory pulmonary edema; systolic blood pressure (SBP) > 90mmHg; Low output state (e.g. oliguria) but normal lactate levels; Requirement for continuous intravenous diuretic; Requirement for urgent valvular intervention

b. TYPE 3: SBP > 90 mmHg; might be in low cardiac output State; Episodes of pulmonary edema; Intermittent IV diuretics; May Require valvular intervention
c. Type 4: Mild-Moderate HF; Might require oral diuretic therapy; Typically treated medically, but late LV remodeling may be very unfavorable; Role of valvular intervention is uncertain.
4. Written informed consent

Exclusion criteria

1. Primary MR (e.g. papillary muscle rupture)
2.Clinical presentation of AMR fulfills the following scenario, as proposed by Shuvy et al. [1]:
TYPE 1: Cardiogenic shock: SBP < 90 mmHg + pulmonary edema; Elevatored lactate levels; Requirement for inotropic therapy and/or mechanical support; Requirement for urgent valvular intervention.
3.EF <= 25%
4. Accepted for CABG
5.Leaflet anatomy which may preclude MitraClip implantation, proper MitraClip positioning on the leaflets or sufficient reduction in MR by the MitraClip. This evaluation is based on transesophageal echocardiogram (TEE) evaluation of the mitral valve.
6. Subjects in whom transesophageal echocardiography (TEE) is contraindicated or high risk.
7. Known hypersensitivity or contraindication to procedural medications which cannot be adequately managed medically.
8. Pregnant or planning pregnancy within next 48 months.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NCT06282042
CCMO	NL86971.100.24