A RANDOMIZED STUDY OF THE MITRACLIP DEVICE IN HEART FAILURE PATIENTS WITH CLINICALLY SIGNIFICANT FUNCTIONAL MITRAL REGURGITATION

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To further study the safety and effectiveness of the MitraClip system in the treatment of clinically significant functional mitral regurgitation in patients with New York Heart Association (NYHA) Functional Class III or Class IV chronic heart...

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

Summary

ID

NL-OMON39358

Source
ToetsingOnline

Brief title
THE RESHAPE-HF TRIAL

Condition

- Cardiac valve disorders

Synonym
Functional mitral regurgitation - Chronic Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott Vascular

Intervention

Keyword: Chronic Heart failure, Functional Mitral Regurgitation, MitraClip, Mitral valve

Outcome measures

Primary outcome

Hierarchical composite of all-cause mortality and recurrent heart failure hospitalizations..

Secondary outcome

• Composite of all-cause mortality, stroke, myocardial infarction, new need for renal replacement therapy and non-elective cardiovascular surgery for device related complications in the Device group at 30 days

• Mitral Regurgitation (MR) severity of mild or mild-to-moderate at 12 months

• Change in Left Ventricular End Diastolic Volume (LVEDV) at 12 months over baseline

• Change in Left Ventricular End Systolic Volume (LVESV) at 12 months over baseline

• Change in 6 Minute Walk Test (6MWT) distance at 12 months over baseline

• Change in Quality of Life (QoL) score, as measured by Kansas City Cardiomyopathy Questionnaire (KCCQ) at 12 months over baseline

• New York Heart Association (NYHA) Functional Class I/II at 12 months over baseline

In addition also Health Economic Endpoints:

• Device procedure cost including device and associated equipment, operative time, staff time and length of hospital stay (Intensive Care Unit (ICU) and non-ICU)

• All-cause re-hospitalizations (time to each hospitalization and length of each hospitalization) at 12 months and 24 months

• Concomitant cardiac treatments (medications and invasive/semi-invasive procedures)

• Discharge location after each hospitalization (e.g., home, home with home health care, skilled nursing, long-term acute care)

• Inpatient and outpatient physician visits (related to MR and heart failure excluding scheduled trial-related follow-up visits)

• Management of device-related adverse events

Study description

Background summary

The trial is designed to provide additional evidence concerning the appropriate recommendations for the use of the MitraClip system in the treatment of chronic heart failure patients with significant functional mitral regurgitation (MR). Additionally, the trial will collect evidence regarding health economics of the MitrClip system for use in this patient population.

Study objective

To further study the safety and effectiveness of the MitraClip system in the treatment of clinically significant functional mitral regurgitation in patients with New York Heart Association (NYHA) Functional Class III or Class IV chronic heart failure.

Study design

Prospective, randomized, parallel-controlled, multi-center clinical evaluation of the MitraClip device plus optimal standard of care therapy (Device group) compared to optimal standard of care therapy alone (Control group).

Eligible subjects will be randomized in a 1:1 ratio to the Device group or Control group.

Intervention

The Device group will recieve the optimal standard of care therapy and the MitraClip placement.
The Control group will only receive the optimal standard of care therapy (by ESC guidelines for heart failure).
All the subject must remain in their randomized group for a minimum of 12 months. Subjects in the control group will be allowed to undergo the mitraclip procedure only after the subject has completed 24months follow up visit or the last randomized subject has completed a 12MFU visit , whichever occurs earlier.

Study burden and risks

Heart failure patients with clinically significant functional MR have limited options for the treatment of their valvular insufficiency. Current options to treat their FMR include medical management and occasionally mitral valve repair or replacement surgery.
Medical management of heart failure patients with FMR is intended to reduce symptoms and improve quality of life; yet medical management does not treat the mechanical malcoaptation of the mitral valve leaflets, and therefore is not a long-term treatment solution for their MR. Ongoing MR in medically managed patients eventually leads to deterioration in cardiovascular function and thus, worsening heart failure. The prognosis is poor for heart failure patients with FMR who are primarily on medical therapy, as the main cause of the heart failure is not effectively addressed by available medical therapy.
In this clinical trial, the overall risk versus benefit analysis of the MitraClip System is based on weighing the potential risks and benefits of the MitraClip System combined with optimal medical therapy against the known risks and benefits associated with optimal medical therapy alone.
The risks associated with the MitraClip procedure can be grouped into two categories. First, there are potential risks associated with standard cardiac catheterization, including transseptal catheterization, the transesophageal echocardiogram (TEE) probe and the potential risks of general anesthesia. Second, there are the potential risks uniquely associated with the use of the MitraClip System.
For details, please refer to Clinical Investigation Plan 12-513: Version 2.0 dd 2Oct2012 page 81-83

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

- Clinically significant functional mitral regurgitation (moderate-to-severe or severe MR), as defined by European Association of Echocardiography, within 90 days prior to randomization and confirmed by the echocardiograpphy corelab.
- Age between 18 years and 90 years old
- Assessed by the investigator to be on optimal standard of care therapy for heart failure, as described in Section 5.7 Baseline Treatment Optimization, for at least 4 weeks with no dose changes of heart failure drugs (with the exception of diuretics) during the last 2 weeks immediately prior to randomization.
- Documented New York Heart Association Class III or Class IV heart failure, despite optimal standard of care therapy 50, within 90 days preceding randomization. Therapy 50 means optimal medical and/or device therapy includes optimal stabilization of symptoms with the use of appropriate evidence based therapies including medicines, revascularization

and cardiac resynchronization therapy with or without cardioverter defibrillator as indicated per ESC guidelines(see for more explanation "aanvullende opmerkingen"..)
- Minimum of one documented hospitalization (acute care admission or emergency room visit) for heart failure within 12 months preceding randomization OR values of at least 350 pg/mL for BNP or at least 1400 pg/mL for NT-proBNP after optimal medical and/or device management within 90 days preceding randomization
- Left ventricular ejection fraction (LVEF) >= 15% and <= 40% determined by echocardiography within 90 days prior to randomization and confirmed by the ECL
- LVEDD >=55mm determined by TTE within 90 days prior to randomization and confirmed by the ECL

Exclusion criteria

For all Excl criteria see page 36-38 of CIP 2.0
- Mitral regurgitation is primarily due to degenerative disease of the mitral valve apparatus (Degenerative MR), as determined by TEE.
- Status 1 heart transplant or prior orthotopic heart transplantation
- Introduction of a new heart failure drug class within the last 4 weeks prior to randomization
- Any cardiovascular hospitalization within the last 2 weeks immediately prior to randomization.
- Evidence of acute coronary syndrome, TIA or Stroke within 90 days prior to randomization.
- Any percutaneous cardiovascular intervention, carotid surgery, cardiovascular surgery or atrial fibrillation ablation within 90 days prior to randomization
- Mitral valve surgery is considered a therapeutic option for the subject
- Renal replacement therapy
- 6MWT distance > 450 meters
- Contraindication to transseptal catheterization
- subjects in whom TEE is contraindicated
- Active infections requiring current antibiotic therapy
- Severe right ventricular failure or severe tricuspid regurgitation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2013
Enrollment:	64
Type:	Actual

Medical products/devices used

Generic name:	Mitraclip
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-02-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-11-2013
Application type:	Amendment
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
Other	http://www.clinicaltrials.gov
CCMO	NL41064.100.12