Ventricular ContractiLe reserve for the optImization of Patient SELECTion for MitraClip implantation. (CLIP SELECT-study)

Published: 16-04-2015
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Primary Objective: The association between the functional improvement (change in VO2 max) and DSE parameters will be determined. In this way the diagnostic characteristics of DSE will be investigated.Secondary Objective(s): The influence of the...

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

Summary

ID

NL-OMON42366

Source
ToetsingOnline

Brief title
CLIP SELECT-study

Condition

- Cardiac valve disorders

Synonym
mitral valve leakage, mitral valve regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Contractile reserve, MitraClip, Mitral valve Regurgitation, Patient selection

Outcome measures

Primary outcome

-Predictive value of the contractile reserve on functional improvement.

-Elucidate the remodelling capacity of the LV and RV.

Secondary outcome

-Predictive value of heart failure markers on functional improvement.

-Predictive value of co-morbidities on functional improvement.

Study description

Background summary

Patient selection is of high importance to ensure an effective MitraClip implantation. Factors such as Left and Right Ventricular Function (respectively LVF and RVF) and specifically ventricular contractile reserve, will influence this efficacy. In case of a poor cardiac function with no contractile reserve, a patient might not benefit as much as in case of a present contractile reserve.
It may thus be a better strategy to treat a patient in time, before the ventricles have deteriorated beyond repair, than to continue medical therapy only. Likewise, it could be that in case of absent contractile reserve a patient will not benefit sufficiently from MitraClip therapy.
Therefore, further knowledge of the contractile reserve of the Left Ventricle (LV) and Right Ventricle (RV) in patients referred for mitral valve therapy is useful to optimize patient and treatment selection. Dobutamine Stress Echocardiography (DSE) is a qualitatively good and applicable modality for this purpose and it provides useful information on the dynamic character of the mitral regurgitation.
Apart from cardiac factors, comorbidities are determinants of patient outcome, and will thus influence the efficacy of MitraClip treatment. Before acceptance for MitraClip therapy according to guidelines, a life expectancy of at least one year is required, which is often determined by comorbidity. But which

factors, and to which extent these factors play a role, is not yet known. To gain insight into these factors will allow better patient selection in the future. The MitraClip implantation will be more effective and less patients are unnecessarily exposed to the risks of such a procedure.

Study objective

Primary Objective: The association between the functional improvement (change in VO2 max) and DSE parameters will be determined. In this way the diagnostic characteristics of DSE will be investigated.

Secondary Objective(s): The influence of the MitraClip implantation on several parameters is analyzed. The influence of the MitraClip on the contractile reserve capacity, change in ejection fraction and change in MR when during DSE will be analyzed. Also, the influence of the MitraClip on the Tricuspid valve Regurgitation (TR) and on the pulmonary pressures will be analyzed. Furthermore, heart failure markers are tracked, such as NT-proBNP, as this has been shown to be predictive of outcomes after MitraClip implantations. The influence the MitraClip on acute hemodynamic effects will be investigated with help of pressure-volume loops. Finally, the role of co-morbidity factors on long-term outcome after MitraClip implantation will be investigated.

With more knowledge of these influences, a more considered patient-specific choice regarding the Mitraclip implementation can be made.

Study design

The study design is an observational cohort study. The duration of the patient inclusion is from April 2015 and April 2017. The duration of the follow-up will continue till April 2019

Study burden and risks

The procedures that have been added to the standard clinical care for research purpose are attempt to be combined with standard appointment to minimize extra hospital visits. Patient will undergo a CPET and a DSE during standard visits. It is intended that these investigations are combined with the standard visits for the screening and the standard MRI. The subject should fill in questionnaires during standard visits. The conductance catheter will be introduced through the sheath which is already introduced for the standard blood pressure measurements. A 8 French sheath must be introduced instead of the standard used 6 French sheath. The Swan-Ganz catheter will be introduced through an extra introduced venous sheath on the left. As a result of the measurements, the fluoroscopy time will increase with less than 1 minute. An application for radiation advice is send to dr.ir. G.J.Streekstra.

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

- Patients who are suffering from MR and accepted for MitraClip screening
- Age > 18 years old
- Provided written informed consent

Exclusion criteria

- Incapable of giving informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL52635.018.15