Magnetic Resonance Imaging study to evaluate the effect of MitraClip implantation

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29348

Source
NTR

Brief title
MRI-MC

Health condition

Mitral regurgitation; percutaneous mitral valve repair; MitraClip.

Mitralisklepinsufficiëntie; percutane mitralisklep reparatie.

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Abbott B.V.

Intervention

Outcome measures

Primary outcome

Change in left ventricular end diastolic volume (EDV) and myocardial blood flow (MBF).

Secondary outcome

End systolic volume, left ventricular ejection fraction, stroke volume, regurgitant volume, mitral annulus diameter, left atrial size, left ventricular mass, wall strass, native T1, extracellular volume.

Study description

Background summary

We aim to study the effect of the MitraClip implantation on myocardial performance as determined by changes in left ventricular end diastolic volume and myocardial perfusion, in 45 patients in the University Medical Center Groningen.

Study objective

We hypothesize that percutaneous edge-to-edge mitral valve repair using MitraClip reduces left ventricular end diastolic volume and improves myocardial perfusion.

Study design

T0a (inclusion)

T0b (first CMR assessment)

T1 (MitraClip implantation)

T2a (second CMR assessment)

T2b (outpatient clinic visit at 6 months)

T3 (outpatient clinic visit at 1 year)

Intervention

Cardiovascular magnetic resonance imaging (CMR) before MitraClip implantation and at 4 months after implantation.

Contacts

Public
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The Netherlands
Scientific
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The Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must be scheduled for percutaneous mitral valve repair using the MitraClip.

Exclusion criteria

Patients will be excluded from this study for any of the following reasons:

- not eligible for percutaneous MitraClip implantation;

- pregnancy or lactation;

- contraindication for CMR imaging (known claustrophobia; tattoos containing metallic dyes; body mass >250 kg;, ferromagnetic objects in the body, e.g. non-MRI compatible pacemaker);

- general condition which, according to the clinical judgment of the investigator and/or treating physician, does not allow the patient to participate in the study;.

- patients with a high degree atrioventricular block will be excluded from adenosine administration.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-2015
Enrollment:	45
Type:	Unknown

Ethics review

Positive opinion

Date:	15-03-2017
Application type:	First submission

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
NTR-new	NL6354
NTR-old	NTR6538

Register	ID
Other	METc Groningen : 2015.176

Study results

Summary results
None so far.