Long-term follow-up after restrictive mitral annuloplasty for functional mitral regurgitation.

Published: 09-12-2015
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To evaluate long-term clinical and echocardiographic outcome after restrictive mitral annuloplasty for functional mitral regurgitation.

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

Summary

ID

NL-OMON42573

Source
ToetsingOnline

Brief title
Follow-up after RMA

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
Mitral regurgitation

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Mitral regurgitation, Mitral valve, Restrictive mitral annuloplasty

Outcome measures

Primary outcome

Cardiac mortality.

Secondary outcome

- All-cause mortality

- Valve-related mortality

- Hospital readmissions for heart failure and other cardiovascular causes

- Major adverse valve-related events

- Echocardiographic outcome (atrial and ventricular dimensions, volumes and function; mitral and tricuspid regurgitation, effective orifice area and transvalvular gradients)

- Functional outcome (6-minute walk test, NYHA, CCS)

- Quality of life (SF-36 questionnaire, Minnesota Living with Heart Failure Questionnaire)

Study description

Background summary

Little information exists on long-term outcome after restrictive mitral annuloplasty. At Leiden University Medical Center, restrictive mitral annuloplasty rings have been implanted since 2000.

Study objective

To evaluate long-term clinical and echocardiographic outcome after restrictive

mitral annuloplasty for functional mitral regurgitation.

Study design

Single-center observational study.

Study burden and risks

Minimal burden and no risks are expected.

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 have undergone a restrictive mitral annuloplasty between the years 2000 and 2014 at the LUMC.

Exclusion criteria

Patients in whom the restrictive annuloplasty ring has been explanted.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Date:	09-12-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL53993.058.15