# SEP-study: The assessment of normal values in Stress Echocardiographic Parameters in patients after successful mitral valve repair for organic mitral valve regurgitation

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To determine normal values in stress echocardiographic parameters in asymptomatic patients at least 6 months after successful MV repair for organic MV regurgitation. These normal values for non-invasive 2D stress echo testing are of utmost...

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

## Summary

### ID

NL-OMON39560

**Source**
ToetsingOnline

**Brief title**
SEP-study

### Condition

- Cardiac valve disorders

**Synonym**
mitral valve function, mitral valve repair

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht
**Source(s) of monetary or material Support:** ICIN

## Intervention

**Keyword:** 2D-echocardiography, 3D-echocardiography, Exercise stress echocardiography, Normal values, Post mitral valve repair

## Outcome measures

### Primary outcome

To determine normal values in stress echocardiographic parameters in asymptomatic patients at least 6 months after successful MV repair, including but not limited to the following 2D stress echo parameters: mean gradient (MG) and peak gradient over the repaired MV, systolic pulmonary artery values (sPAP), left ventricular end diastolic dimensions (LVEDD), left ventricular end systolic dimensions (LVEDS), left atrium (LA) dimensions, ejection fraction (EF), mitral valve area (MVA) and severity of MV regurgitation (grade 1-4).

### Secondary outcome

Secondary objective is to compare 2D echocardiographic parameters during physical exercise to 3D stress echo parameters (including but not limited to the following 2D and 3D stress echo parameters: mean gradient (MG) and peak gradient over the repaired MV, systolic pulmonary artery values (sPAP), left ventricular end diastolic dimensions (LVEDD), left ventricular end systolic dimensions (LVEDS), left atrium (LA) dimensions, ejection fraction (EF), mitral valve area (MVA) and severity of MV regurgitation (grade 1-4)).

# Study description

### Background summary

Surgical treatment is the only approach with potentially defined clinical success for organic mitral valve (MV) regurgitation. Recurrent or persistent complaints after initial successful MV repair is a clinical challenge in current practice. Especially when echo parameters at rest are within or near normal ranges and patients presenting disproportionately symptomatic in relation to the observed results. However, while MV regurgitation is a hemodynamic disease, currently used 2-dimensional (2D) transthoracic echocardiography (TTE) at rest lacks information about hemodynamic changes. Physical 2D stress echocardiography is a promising technique to complement nowadays rest TTE in order to improve interpretation of hemodynamic changes. In addition, 3-dimensional (3D) echo is useful to describe the morphoanatomy and physiology of the MV during stress and to define an approach for accurate quantification. However,2D normal values for exercise echo are lacking in this postoperative patients cohort. A observational trial to determine 2D normal values in stress echocardiographic parameters in asymptomatic patients after successful MV repair for organic MV regurgitation, is therefore highly needed.

### Study objective

To determine normal values in stress echocardiographic parameters in asymptomatic patients at least 6 months after successful MV repair for organic MV regurgitation. These normal values for non-invasive 2D stress echo testing are of utmost importance to correctly and accurate interpret stress echo results during postoperative follow-up and to improve clinical decision making in patients post MV repair. In addition 2D stress echo parameters will be compared to 3D echocardiographic measurements during physical exercise.

### Study design

Single centre, cross-sectional study.
We will perform physical stress echoes (2D and 3D) in 25 study patients. Patients will be recruited from the heart valve surgery database of the UMC Utrecht.

### Study burden and risks

An extra follow-up visit at least 6 months after successful MV repair is planned in view of the trial at the UMC Utrecht study center. During this visit (approximately taking 1 hour) an exercise echocardiogram will be performed on a semi-supine bicycle. Rare but serious complications in exercise testing are reported in one out of ten thousand patients, which can be easily stratified in

advance based on resting electrocardiogram (ECG), medical history and risk factors. Exercise testing is immediately stopped when complaints occur. Safety is furthermore guaranteed by the attendance of a medical doctor during the exercise test.

# Contacts

**Public**
Universitair Medisch Centrum Utrecht

Heidelberglaan 100 E 03 511
Utrecht 3584 CX
NL
**Scientific**
Universitair Medisch Centrum Utrecht

Heidelberglaan 100 E 03 511
Utrecht 3584 CX
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Age >=18 years;
- Male or female from all ethnicities;
- At least 6 months post successful, isolated MV repair. Successful MV repair: when there is no or grade 1+ residual or recurrent MV regurgitation, MG <10 mmHg and MVA >1.5 cm2 after MV surgery and during follow-up. Isolated MV surgery may include a coronary artery bypass graft (CABG);

- No symptoms (asymptomatic). Symptoms are defined as subjective limitations of exercise capacity or complaints expressed by the patient and confirmed by the treating cardiologist;

### Exclusion criteria

- Pulmonary hypertension >50 mmHg at rest;
- Atrial fibrillation (AF) at time of study related stress echo testing;
- Known contraindication or incapability to perform peak exercise or inability to perform physical stress testing;
- LVEF <45%;
- NYHA class II and more;
- Other heart valve disease of more than mild severity;
- Concomitant surgery during MV repair, e.g. MAZE, TVP procedure;
- Heart valve surgery prior to MV repair;
- Congenital heart disease;
- Disabling comorbidity, e.g. chronic obstructive pulmonary disease (COPD);
- Unable to provide informed consent.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-02-2015 |
| Enrollment: | 25 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 16-10-2014 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 | NL39865.041.14 |