# Hemodynamic characterization of the respect and resect approaches in mitral valve repair surgery: a 4D-flow MRI study (RES-P-ECT 4D trial)

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The aim of this study is to investigate potential differences in blood flow patterns, wall shear stress and energy loss in patients after mitral valve repair with the resect and respect approach.

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

## Summary

### ID

NL-OMON53892

**Source**
ToetsingOnline

**Brief title**
4D flow after surgical respect or resect approach (RES-P-ECT 4D trial)

### Condition

- Cardiac valve disorders

**Synonym**
heart valve leakage, Mitral valve regurgitation

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC

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

## Intervention

**Keyword:** 4D flow MRI, Mitral valve repair, Resect, Respect

## Outcome measures

### Primary outcome

The main study parameters are;

- blood flow velocity (kinetic energy and turbulent kinetic energy) in the left atrium, left ventricle, over the aortic valve, in the ascending aorta, the aortic arch and the descending aorta

- energy loss in the left atrium, left ventricle, over the aortic valve, in the ascending aorta, the aortic arch and the descending aorta

- trans-valvular flow quantification of the mitral valve

All outcomes will be compared to available reference values in healthy subjects.

### Secondary outcome

Routine MRI parameters;

- enddiastolic and endsystolic volumes

- stroke volume

- ejection fraction

# Study description

### Background summary

Primary mitral regurgitation due to degenerative valve disease is a common cardiac disease. Mostly, the mechanism behind this disease is a prolapse of the posterior 2 leaflet segment of the mitral valve. Ultimate treatment for patients suffering from this disease is mitral valve repair surgery. For this procedure there are two main techniques which are considered equal. These are the 1) resect approach in which the diseased leaflet segment is resected and the remaining segments are sutured together and the 2) respect approach in which the prolapsed leaflet segment is resuspended by implantation of artifical chordae.

Earlier studies have investigated whether there are differences between these two approaches regarding clinical outcome. However, results show outcomes in favor of both strategies. This indicates the need for a more precise approach of investigation.
Hemodynamic changes after surgery play an important role in the clinical outcome of these patients. Yet, despite the fact that these surgical approaches are performed for more than 30 years and results for both techniques are satisfactory, knowledge about the effect on post-operative blood flow patterns in these patients remains limited.

### Study objective

The aim of this study is to investigate potential differences in blood flow patterns, wall shear stress and energy loss in patients after mitral valve repair with the resect and respect approach.

### Study design

Prospective single center pilot study

### Study burden and risks

Since all the elements of this study are harmless and carry no risk, the overall risk is considered minimal.

# 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 surgical mitral valve repair - more than 1 year ago
- for mitral regurgitation due to a prolapse of the P2 leaflet segment of the mitral valve.

## Exclusion criteria

- Have underwent a cardiac reoperation after the initial mitral valve repair procedure
- Have major comorbidity besides mitral regurgitation
- Are under the age of 18.
- Have claustrophobia or another contra-indication for MRI.
- Are not able to provide written informed consent.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2023 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 22-03-2023 |
| Application type: | First submission |
| 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 | NL83026.018.22 |