

# Feasibility of Magnetic Resonance Elastography of the Breast

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To test the feasibility of breast MR elastography and explore the viscoelastic parameters of (1) normal breast tissue, of (2) breast tumours and of (3) scar tissue in the breast after lumpectomy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Breast disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43879

### Source

ToetsingOnline

### Brief title

Breast MR elastography

### Condition

- Breast disorders

### Synonym

breast tumours

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** Breast, Elastography, MRI

## Outcome measures

### Primary outcome

The viscosity and elasticity (kPa) of normal breast tissue, of breast tumours and of the post-operative breast tissue.

### Secondary outcome

NA

## Study description

### Background summary

MR Elastography can be used to obtain biomechanical information (elasticity, viscosity) of tissue by measuring and displaying propagating mechanical waves. Alteration of tissue biomechanics plays a central role in disease processes. Currently, breast MR imaging does not involve the evaluation of tissue biomechanics.

### Study objective

To test the feasibility of breast MR elastography and explore the viscoelastic parameters of (1) normal breast tissue, of (2) breast tumours and of (3) scar tissue in the breast after lumpectomy.

### Study design

Single-centre, non-randomised prospective exploratory imaging study.

### Study burden and risks

For all participants, participating in this study will be entirely non-invasive: for the MRI no contrast agent will be administered. Patients with a breast tumor (group 2) will have the MR elastography scan added to the breast MRI which they will receive as part of standard care. The total time of the MRI will therefore be 40 instead of 30 minutes.

Participants from group 1 and 3 (volunteers and patients after lumpectomy) will have additional anatomical MR series in addition to the MR elastography scan, without the administration of contrast agent. The time in the MRI will be approximately 30 minutes.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- \* Female, 18 years of age or older.
- \* Healthy volunteer with no medical history with respect to the breast (group 1), known breast cancer (group 2) or history of lumpectomy (group 3).
- \* The capacity to understand the patient information sheet and the ability to provide written informed consent.

## Exclusion criteria

- Standard contraindications to MR imaging (e.g. cardiac pacemaker, cochlear implant, claustrophobia, pregnancy).
- Known chronic kidney disease (for those patients who will receive the standard breast MRI with Gadolinium for the purpose of this study and not as part of routine care).

## 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): 25-09-2015

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 26-06-2015

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**

<b>Register</b>	<b>ID</b>
CCMO	NL52963.018.15