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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast disorders
Study type	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 constrast agent. The time in the MRI will be approximately 30 minutes.

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

* 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

Register	ID
CCMO	NL52963.018.15