Feasibility of ultra high field 7.0 Tesla MRI for the detection of breast cancer

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Feasibility of 7T beast MRI for the detection of breast cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON34075

Source
ToetsingOnline

Brief title
7T breast MRI study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 7.0 Tesla MRI, breast cancer, breast neoplasm, Ultra high field MRI

Outcome measures

Primary outcome

The primary endpoint is the 7T detection rate of stage T1 breast cancer

lesions.

Secondary outcome

- To assess the morphology of the cancer lesions as described in the MRI

BI-RADS

lexicon.

- To assess the kinetics of lesion enhancement.

- To assess the correlation of 7T MRI analysed lesions sizes to the sizes as

determined in

the final pathological analysis.

Study description

Background summary

Every year over 10.000 Dutch women are diagnosed with invasive breast cancer. This makes breast cancer the cancer type with the highest incidence in Dutch women.
When a breast lesion is detected, conventional triple diagnosis, which consists of palpation, mammography and fine-needle cytology, currently with the addition of ultrasound imaging, is performed to establish the diagnosis. Before treatment can be initiated accurate staging needs to be conducted to develop an individualized treatment plan. Staging requires precise knowledge of the size of the index lesion as well as of the presence or absence of lesions in other quadrants of the breast.
Magnetic resonance imaging has an additional value in the staging of breast cancer due to its capability to depict multicentric and multifocal disease, to assess the tumor in a three-dimensional way and to detect lesions in dense breast tissue. In recent years there has been an increasing interest in MRI as a non-invasive diagnostic modality for the work-up of suspicious breast lesions. The sensitivity of MRI for diagnosing breast cancer is over 90% with

specificity around 70%
Recently ultra-high field 7.0 Tesla MRI has become clinically available. The availability of ultra high field 7T MRI offers new diagnostic possibilities: due to the very high magnetic field strength of the scanner, images can be acquired at a higher spatial resolution allowing smaller structural detail to be depicted. For breast cancer this would mean not just the detection of smaller lesions, but also better morphologic classification of detected lesions and better delineation of lesion extent.

Study objective

Feasibility of 7T beast MRI for the detection of breast cancer.

Study design

Prospective cohort study.

Study burden and risks

The patient will have to fill out an MRI safety form before entering the 7T MRI area. An iv catheter will be inserted to administer contrast agent used during the MRI exam. The patient will undergo one MRI exam.
As far as is known there are no short- or long term risks involved in having an MRI examination. Some patient will experience light flashes or tingling due to the very high magnetic field of the 7 Tesla MRI. This will immediately disappear as soon as leaving the scanning area. Participants are not requested to take any precautions or actions following to or prior to the MRI exam.
The contrast agent administered during the exam is daily used in clinical practice during imaging. In rare cases an allergic reaction can occur, such as an itch, nausea or small bumps on the skin. In the vast majority of cases these symptoms pass quickly. In extremely rare cases acute allergic reactions can occur, in patients with known contrast allergies, which do require medical treatment. Therefore these patients are excluded from participation in this study. For safety reasons at all times a patient is scanned on the 7T MRI and contrast is given a medical doctor will be present.

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

- 18 years or older
- Female patients
- A breast lesion <2cm with BIRADS 4c or higher classification on mammography, US and/or lower field MRI
- Lesion with maximum dimension of 2 cm

Exclusion criteria

- Any prior surgery or radiotherapy to the ipsilateral breast
- Karnofsky score <= 70
- Pregnant or lactating women
- Contra-indications to MRI scanning according to the 7T screening list of the UMCU
- Contra-indications to injection of gadolinium-based contrast-agent, including known prior allergic reaction to any contrast-agent, and renal failure, defined by GFR < 30mL/min/1.73m2.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2010
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

ID: 20303
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32664.041.10
OMON	NL-OMON20303