Contrast-enhanced MR imaging of the breast at 7T and 3T in the same patients.

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The objective of our study is to to assess the diagnostic performance of 7T CE breast MRI in comparison to the current clinical standard of 3T MRI and histopathology on a intra-individual basis.

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

Summary

ID

NL-OMON40016

Source
ToetsingOnline

Brief title
7T vs. 3T 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 / A sister's Hope

Intervention

Keyword: 3.0 Tesla MRI, 7.0 Tesla MRI, breast cancer, intra-individual comparison

Outcome measures

Primary outcome

To assess the diagnostic performance of 7T CE Breast MRI in comparison with the clinical standard of 3T MRI (by using the BI-RADS MRI lexicon) and histopathology, on a intra-individual basis.

Secondary outcome

- To assess the diagnostic performance of 7T versus 3T on a per lesion basis.

- To assess the correlation of 7T MRI lesion size to 3T MRI lesion size and to lesion size determined on histopathology after surgery.

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, 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 is required as well as of the presence or absence of lesions in other quadrants of the breast.
Magnetic resonance imaging has 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 means not just detection of smaller lesions, but also better morphologic classification of detected lesions and better delineation of lesion extent.
The preliminary results of our nearly finished technical feasibility study of CE breast MRI at 7T (NL32664.041.10) has concluded that contrast-enhanced 7T breast MRI is technically feasible and reasonably well tolerated. Both morphology as well as kinetic assessments could be conducted, in accordance with the BI-RADS-MRI criteria. The next step is to assess the diagnostic performance of 7T CE-MRI in comparison with the current diagnostic standard of 3T MRI and histopathology.

Study objective

The objective of our study is to to assess the diagnostic performance of 7T CE breast MRI in comparison to the current clinical standard of 3T MRI and histopathology on a intra-individual basis.

Study design

This is a prospective cross-sectional study.

Study burden and risks

The patient burden consists of an MRI examination form that needs to be filled out before entering the MRI area. An iv catheter will be inserted to administer the contrast agent used during the MRI exam, before each of the exams. The patient will undergo two MRI exams, on two separate days.

As far as is known there are no short- or long term risks involved in having an MRI scan. Some patient will experience light flashes or tingling due to the very high magnetic field, especially at 7T. This will immediately disappear as soon as leaving the magnetic field. 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 known with contrast allergies, which do require treatment. Therefore these patients are excluded from participation in this study. Furthermore, patients with renal impairment (GFR <30mL/min/1.73m2) are excluded because of the associated risk of NSF when receiving a gadolinium based contrast agent. 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 BI-RADS 4 or higher classification for a lesion detected at mammography and/or ultrasound

Exclusion criteria

Surgery or radiotherapy to the ipsilateral breast up to one year before inclusion

Prior treatment with chemotherapy
Karnofsky score <= 70
Pregnant or lactating women
Contra-indications to MRI scanning according to our hospitals 3T or 7T MRI screening-guideline
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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-04-2014
Application type:	Amendment
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: 27773
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36419.041.11
OMON	NL-OMON27773