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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27773

Source
Nationaal Trial Register

Brief title
7T vs. 3T beast MRI study

Health condition

breast cancer, breast neoplasia

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

The primary aim is to assess the diagnostic performance of 7T CE breast MRI. This is done by comparing the final 7T BI-RADS-MRI classification to the final 3T BI-RADS-MRI classification and to histopathology obtained after biopsy and surgery.

Secondary outcome

1. To establish the per-lesion diagnostic accuracy of 7T;

2. Comparison of lesion size as determined at 7T, 3T and final pathology.

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

This is a prospective cross-sectional study aimed at assessing the diagnostic performance of 7T CE breast MRI compared to the clinical standard of 3T MRI and histopathology, on a intra-individual basis.

Study design

Patients with a BI-RADS 4 of higher classification will be submitted to two MRI exams.

The endpoint of follow-up for all included patients will be final histological evaluation.

Intervention

Two contrast-enhanced breast MRI scans; 7 Tesla MRI & 3 Tesla MRI.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Female patients;

3. A BI-RADS 4 or higher classification for a lesion detected on mammography and/or ultrasound.

Exclusion criteria

1. Any prior surgery or radiotherapy to the ipsilateral breast;

2. Karnofsky score <= 70;

3. Pregnant or lactating women;

4. Contra-indications to MRI scanning according to hospitals 7T MRI screening guidelines;

5. 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:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2011
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40016
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2902
NTR-old	NTR3048
CCMO	NL36419.041.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40016

Study results

Summary results
N/A