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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20303

Source Nationaal Trial Register

Brief title 7T breast MRI study

Health condition

Breast tumor Breast neoplasm

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)

Visiting address

------Heidelberglaan 100 3584 CX Utrecht

The Netherlands

Postal address

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3508 GA Utrecht The Netherlands

Phone: +31 (0)88 75 555 55

Source(s) of monetary or material Support: Pink Ribbon

Intervention

Outcome measures

Primary outcome

The primary endpoint is the 7T detection rate of stage T1 breast cancer lesions in a cohort of women with BI-RADS 4c of higher lesion at mammography, ultrasound and/or lower field strength MRI.

Secondary outcome

1. To assess the morphology of breast cancer at 7T as described according to the MRI BI-RADS lexicon;

2. To assess the kinetics of lesion enhancement at 7T;

3. To assess the correlation of 7T MRI lesion size and lesion size as determined by final pathological analysis.

Study description

Background summary

Every year more than 10.000 Dutch women are diagnosed with breast cancer. This makes breast cancer the cancer with the highest incidence in Dutch women.

When a breast lesion is detected conventional triple diagnosis - 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.

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 threedimensional way and to detect lesions in dense breast tissue. Recently ultra-high field 7.0 Tesla MRI has become clinically available. 7T breast MRI offers new diagnostic abilities that have the potential to improve the staging of breast cancer patients.

Before 7T MRI can be implemented in clinical practice, validation is needed.

This is a prospective cohort study aimed at validating the 7T detection rate of breast cancer. The validation will be based on a detailed 7T MRI compared to histological correlation, where histology will be regarded the golden standard.

Study objective

This is a single centre prospective cohort study aimed at the technical feasibility of 7T contrast enhanced breast MRI.

Study design

Patients with a BI-RADS 4c or higher classification will be submitted to one contrast enhaced 7T MRI exam before a biopsy will be performed.

The endpoint of follow-up for all included patients is the final histological evaluation, which in most patients will be after surgery; mastectomy or lumpectomy.

Intervention

N/A

Contacts

Public

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Eligibility criteria

Inclusion criteria

- 1. 18 years or older;
- 2. Female patients;

3. A BI-RADS 4c or higher lesion \leq 2 cm on mammography, ultrasound and/or lower field strength MRI.

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

Control: N/A , unknown	
Allocation:	
Intervention model:	
Study type:	

Observational non invasive Parallel Non controlled trial

Recruitment

NL Recruitment status:

Recruitment stopped

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Start date (anticipated):	01-09-2010
Enrollment:	20
Туре:	Actual

Ethics review

Positive opinion	
Date:	29-07-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34075 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2329
NTR-old	NTR2435
ССМО	NL32664.041.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34075

Study results

Summary results

N/A