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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27773

Bron
NTR

Verkorte titel
7T vs. 3T beast MRI study

Aandoening

breast cancer, breast neoplasia

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-08-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40016
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A