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

Gepubliceerd: 29-07-2010 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20303

Bron
Nationaal Trial Register

Verkorte titel
7T breast MRI study

Aandoening

Breast tumor
Breast neoplasm

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)

Visiting address

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Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 three-dimensional 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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Wetenschappelijk

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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 4c or higher lesion ≤ 2 cm on mammography, ultrasound and/or lower field strength MRI.

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:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2010

Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-07-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34075
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A