Feasibility of ultra high field 7.0. Tesla MR Spectroscopy for breast cancer detection and monitoring of neo-adjuvant chemotherapy efficacy

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Validation of 7T breast MRS for monitoring of neo-adjuvant chemotherapy in patients with breast cancer.

Ethical review	Not approved
Status	Will not start
Health condition type	Breast neoplasms benign (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON35742

Source
ToetsingOnline

Brief title
7T MRS breast cancer study

Condition

- Breast neoplasms benign (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: VENI-DK

Intervention

Keyword: 7.0 Tesla MRS, breast cancer, breast neoplasm, Ultra high field MRS

Outcome measures

Primary outcome

1. Sensitivity of 7T MRS detection of histological proven breast cancer. The in

vivo 7T MRS data will be compared to ex vivo measurements with HR-MAS and LC-MS.

2. Sensitivity of 7T MRS to monitor neo-adjuvant chemotherapy effects in

membrane metabolism

Secondary outcome

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Study description

Background summary

Every year over 12.000 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, which consists of 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. Staging requires precise knowledge of the size of the Index Lesion as well as of the presence or absence of lesions in other quadrants of the breast.
Magnetic resonance imaging has an 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 the possibility of detection of smaller lesions, but possibly also better morphologic classification of detected lesions and better delineation of lesion extent. In addition, 7 Tesla MRS offers the possibility to monitor therapy of lesions by means of the detection of phospholipid metabolites that have shown clinical potential as biomarkers for oncological disease in preclinical studies.

Study objective

Validation of 7T breast MRS for monitoring of neo-adjuvant chemotherapy in patients with breast cancer.

Study design

prospective cohort study

Study burden and risks

The patient/volunteer will have to fill out an MRI examination form before entering the 7T MRI area. The patient /volunteer will undergo 1 (group 2 and 3) or 3 MRI / MRS exams.
As far as is known there are no short- or long term risks involved in having an MRS examination. Some patient will experience light flashes or tingling due to the very high magnetic field of the 7 Tesla MRI. This will immediately disappear as soon as leaving the scanning area. Participants are not requested to take any precautions or actions following to or prior to the MRS exam.

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
- Females
- Group 1: patients selected for neo-adjuvant chemotherapy
- Group 2: patients with BIRADS 4c or 5 classification on mammography, US or lower field MRI, selected for surgery
- Group 3: healthy volunteers

Exclusion criteria

- Any prior surgery or radiotherapy to the ipsilateral breast
- Karnofsky score <= 70
- Pregnant or lactating women
- Contra-indications to MRI scanning according to the 7T screening list of the UMCU

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	02-03-2011
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL35649.041.11