Feasibility of ultra high field 7.0 Tesla MR Spectroscopy for monitoring neo-adjuvant therapy efficacy.

Published: 06-06-2011
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON38209

Source
ToetsingOnline

Brief title
Monitoring neo-adjuvant therapy in breast cancer.

Condition

- Breast neoplasms malignant and unspecified (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: NWO-ZonMW: VENI-DK

Intervention

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

Outcome measures

Primary outcome

1. What change in phospholipid metabolites can be detected with 7T MRS during neo-adjuvant therapy in breast cancer?

2. How strong does the change in phospholipid metabolism correlate to the efficacy of therapy as obtained from histology and with tumor volume as measured with standard contrast enhanced MRI.

Secondary outcome

How accurate can phospho-esters be determined with in vivo 7T MRS compared to ex vivo analysis with LC-MS en HR MAS MRS?

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.

Chemo / endocrine / trastuzumab therapy after surgery as well as prior to surgery (neo-adjuvant) is a possible treatment of these tumors. The Dutch regulation for neo-adjuvant therapy states that prior to and halfway through therapy a contrast enhanced MRI scan is made to assess possible tumor progression (volume reduction or -growth), i.e. to assess whether the neo-adjuvant therapy is effective in reducing tumor burden. In case of strong tumour growth direct surgery can be indicated. Unfortunately, there is no evidence in literature that volume reduction is a reliable measure of therapy efficacy.

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, MR Spectroscopy (MRS) at 7 Tesla 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

Feasibility of ultra high field 7.0 Tesla MR Spectroscopy for monitoring neo-adjuvant therapy efficacy.

Study design

Prospective cohort study

Study burden and risks

The patient will have to fill out an 7T MRI contraindication form before entering the 7T MRI area. The patient will undergo 3 MRI / MRS exams.

Two of the MRS scans can be scheduled just after the conventional MRI scan, for this purpose performed at 7 Tesla (prior to and half way therapy). For the last MRS scan at the end of the chemotherapy, just prior to surgery, the patient has to come UMCU specifically for this study.

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 when 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
- breast cancer patients selected for neo-adjuvant therapy

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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	06-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-05-2012
Application type:	Amendment
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

ID: 25351
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL36429.041.11
OMON	NL-OMON25351