Selection of Breast Cancer Patients with Low-risk Tumors using MR Imaging

Published: 08-10-2012
Last updated: 26-04-2024

Primary objective:To establish the accuracy of pretreatment 7T MRI to identify low-risk breast cancers. This will be done by identifying preoperative imaging-based characteristics related to risk factors of cancer relapse in the resection specimens...

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

Summary

ID

NL-OMON36966

Source
ToetsingOnline

Brief title
Patient Risk based on Functional MRI/ PROFILE

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: Breastcancer, low-risk, MRI scan

Outcome measures

Primary outcome

The association between preoperative imaging characteristics and post-operative prognostic markers in resection specimens.

Secondary outcome

Comparison of pre-treatment dynamic contrast-enhanced MRI, MR diffusion-weighted imaging, and magnetic resonance spectroscopy (MRS) at 7T to identify low-risk breast cancers.

Study description

Background summary

Every year more than 13.000 Dutch women are diagnosed with breast cancer. This makes breast cancer the cancer with the highest incidence in Dutch women. Screening programs have allowed detection of breast cancer at earlier stages, but also contributed to the detection of more indolent cancers [1]. Although not every breast cancer is the same, they are treated uniformly depending on stage.

Each step may cause side effects such as infection and bleeding, poor cosmetic outcome, toxicity and fatigue. Hence, breast-conserving therapy pursues a delicate balance between achieving local tumor control and minimizing side effects. Large excision volumesand large radiation doses will improve local control, but will also increase therapy-induced mutilation, resulting in decreased quality of life after treatment.

Patients with more indolent type of cancers will suffer from the same treatment side effects and psychosocial aspects, but are far less likely to die from their disease had they been treated less aggressively. As a result, concern has arisen about potential overtreatment in subgroups of patients with early breast cancer.

To address this concern, minimally or non-invasive techniques have been developed as a substitute for open surgery.
Examples are of such techniques are RF ablation and MRI-guided focused ultrasound39 (MR-HIFU). Their anticipated advantage is reduction of side effects. There are, however, three pitfalls at the moment: 1) It is unknown which patients are at low risk prior to therapy; 2) No resected tissue becomes available to verify that the cancer has been completely removed and 3) No resected tissue is present to examine risk factors that determine if additional systemic drug therapy is necessary.

As a result of these uncertainties, clinical research in non-invasive local therapy of breast cancer has stalled in recent years, and a new impulse is required to make this technique available to the growing population of patients with early-stage breast cancer.

Study objective

Primary objective:
To establish the accuracy of pretreatment 7T MRI to identify low-risk breast cancers. This will be done by identifying preoperative imaging-based characteristics related to risk factors of cancer relapse in the resection specimens: 1) the risk of imaging-occult disease components that may lead to tumor-positive resection margins, 2) the risk of cancer relapse and mortality based on established prognostic models.

Secondary objective:
Comparison of pre-treatment dynamic contrast-enhanced MRI, MR diffusion-weighted imaging, and magnetic resonance spectroscopy (MRS) at 7T to identify low-risk breast cancers.

Tertiary objective:
Comparison of known prognostic markers from core biopsy in combination with 7T MRI on the one hand with the resection specimen on the other hand.

Study design

This is a prospective cohort study aimed at establishing the pre-treatment accuracy of 7T MRI to identify low-risk breast cancers compared with the clinical standard (prognostic markers derived from the resection specimen). Consecutive consenting patients will be included, and the duration of the project will be two years.

Study burden and risks

One single contrast-enhanced MRI examination at 7T prior to surgery. Potential benefits: Preoperative local tumor staging may be improved by MRI, detection of

positive surgical resection margins may be improved with more detailed analysis of resection specimens. Potential risks: Improved local staging may lead to additional diagnostic testing and therapy changes that have not yet been proven to improve patient survival. Allergic reaction to MRI contrast agent may occur in rare cases.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 18 years or older
- Female patients
- Eligible for breast-conserving therapy

Exclusion criteria

- Any prior surgery or radiotherapy to the ipsilateral breast
- Patients planned for neoadjuvant chemotherapy
- Karnofsky score <= 70
- Pregnant or lactating women
- Contra-indications to MRI scanning
Contra-indications to injection of gadolinium based contrast agent

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):	22-01-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	08-10-2012
Application type:	First submission
Review commission:	METC NedMec

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	NL40788.041.12