Contrast-enhanced MR imaging of ductal carcinoma in-situ/invasive lobular carcinoma in supine position: a pilot study

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Primary goal: determine the diagnostic quality of CE-MRI scans acquired in supine positionSecundary goal: determine the accuracy of deformable image registration between prone CE-MRI and non-CE-MRI in supine position as an alternative option

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON41290

Source
ToetsingOnline

Brief title
Supine contrast enhanced MRI of DCIS/ILC

Condition

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

Synonym
ductal carcinoma in-situ/invasive lobular carcinoma, Early stage breast cancer

Health condition

Borst diagnostisch verrichting

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carcinoma In Situ, Contrast enhancement, MRI, Supine

Outcome measures

Primary outcome

The primary goal, diagnostic quality of supine CE-MRI, will be evaluated by 4 radiologists. Each will compare the diagnostic quality with the prone CE-MRI in terms of supine is: better, equal or worse. The image quality of the supine scan will visually be judged on visibility of the lesion extent, in categories, excellent, reasonable, dubious, and impossible.

Secondary outcome

The secondary parameter is the accuracy of deformable image registration between prone CE-MRI scans and supine non-CE-MRI scans. Registration accuracy will be assessed by defining a set of corresponding anatomical landmarks in both images before registration. After registration, the distance between corresponding anatomical landmarks defines the registration accuracy. The identification of landmarks will be performed by two radiologists. The first radiologist will define the landmarks on both the prone and the supine scan. The second radiologist will be provided with the landmarks of the other radiologist on the prone scan, and define the corresponding landmarks on the supine scan. An ANOVA method will be used to define registration accuracy,

taking into account observer variation.

Study description

Background summary

Women with early stage breast cancer are generally treated with breast conserving therapy. This treatment consists of surgical removal of the lesion with a resection margin, followed by radiotherapy. In cases with (a component of) ductal carcinoma in-situ (DCIS) or invasive lobular carcinoma (ILC) the lesion is non-palpable in approximately 80% of patients, hampering the surgical procedure. To guide the surgeon, a contrast enhanced MRI (CE-MRI) is acquired to establish lesion location and extent. Furthermore, a radioactive marker is implanted in the lesion for guidance during surgery. Despite these measures, positive resection margins still occur in approximately 20% of patients.
This pilot study is part of a larger study investigating the possibilities of marking the outer border of the resection area preoperatively using multiple markers. We hypotisize that this could lead to more radical resetions.
CE-MRI scans are generally acquired in prone position, to minimize the influence of breathing motion on the image quality. However, marker insertion and surgery are always performed in supine position. This orientation difference results in an CE-MRI which is anatomically not fully representative for the setup of the interventions.
The goal of this pilot study is to achieve CE-MRI scans in supine position with good diagnostic quality.

Study objective

Primary goal: determine the diagnostic quality of CE-MRI scans acquired in supine position

Secundary goal: determine the accuracy of deformable image registration between prone CE-MRI and non-CE-MRI in supine position as an alternative option

Study design

Within this study patients wil undergo one extra MR imaging session preoperatively. Within this session two MR scans will be acquired in supine position, first without contrast enhancement, subsequently with contrast enhancement. After the imaging session the study participation is finalized for the patient.

Study burden and risks

The burden for the patient is one extra MR imaging session which will take approximately 30 minutes. Also one extra administration of gadolinium contrast is part of the burden. The risks are assessed to be negligible.

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

Histological proven invasive breast cancer with a DCIS (component) or pure ILC
Schedule for breast conserving therapy
A diagnositic contrast enhance MRI in prone position
Informed consent
><= 18 years old

Exclusion criteria

Contra indication for MRI
Contra indication for gadolinium contrast administration

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	26-02-2015
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

No registrations found.

In other registers

Register	ID
CCMO	NL45779.031.13