MRI of regional lymph nodes in cT1-3N0 breast-cancer patients and DCIS (cTisN0) patients

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To assess the influence of sentinel-node biopsy (SNB) on visualization of regional LNs using newly developed MRI techniques.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON41917

Source
ToetsingOnline

Brief title
MILANO

Condition

- Metastases

Synonym
breast cancer, mammary carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, lymph nodes, MRI, regional

Outcome measures

Primary outcome

The primary study parameter is the number of regional LNs detected in pre-sentinel-node biopsy (SNB) and post-SNB MRI scans, taking into account the number of LNs excised during SNB.

Secondary outcome

The secondary study parameter is the number of LNs visible on the standard CT scan that is used for RT planning, in comparison with the pre-SNB and post-SNB MRI scans. Another study parameter is the number of patients who are able to cope with the scanning procedure; this is monitored for all participants. The coping ability for scanning (pre-SNB and post-SNB) determines continuation of the study or the need for adaptation of the scanning protocol.

Study description

Background summary

The standard treatment for breast cancer patients with tumour-positive sentinel node(s) is axillary lymph node dissection (ALND). Based on recent clinical studies (AMAROS and Z0011), ALND is increasingly being omitted, or instead replaced by regional radiotherapy (RT). In current RT planning, the lymph node (LN) areas are delineated indirectly on computed topography (CT) scans by anatomical boundaries, since individual LNs are usually not visible on CT. Consequently, target volumes in regional RT are relatively large, resulting in large high-dose volumes in organs-at-risk (OARs; lungs, heart, brachial plexus). RT-induced morbidity is 10-20%; in order to reduce this rate, more accurate targeting of the LNs is desired. In contrast to CT, magnetic resonance imaging (MRI) allows for direct imaging of the LNs and surrounding anatomy, due to its superior soft-tissue contrast. Using MRI may facilitate delineation of

the individual LNs and the surrounding OARs. This can result in smaller treated volumes, potentially leading to less toxicity. We have developed MRI techniques, in healthy volunteers, to visualize individual LNs. Before considering the addition of MRI to RT planning, or the development of MRI-guided RT techniques of the LNs, it is necessary to test the scanning protocol in patients. This is required since the patient*s anatomy is affected by the sentinel-node biopsy (SNB), which is performed during breast-conserving surgery (BCS) or mastectomy. Therefore, it is important to study the effects of SNB on the visualization of LNs using the new MRI techniques. Moreover, the endurance of patients, after BCS or mastectomy, can differ from healthy volunteers.

Study objective

To assess the influence of sentinel-node biopsy (SNB) on visualization of regional LNs using newly developed MRI techniques.

Study design

In this observational study, first, an MRI scanning protocol is optimized in cT1-3N0 and/or cTisN0 patients. Then, the optimized protocol is applied in cT1-3N0 and/or cTisN0 patients who are to be scanned both before and after sentinel-node biopsy (SNB). Coping ability of all patients is monitored. Influence of SNB on MRI is evaluated by checking consistency of the number of regional LNs detected in pre-SNB and post-SNB MRI scans, which are aimed to be performed on the same day as routine consultations.

Study burden and risks

No benefits are expected for the patients and their treatments will not be affected.
No risks are known for patients undergoing MRI when they are screened according to the MRI safety criteria. No contrast agent will be applied. Two MRI scans will be acquired for each participant: one before sentinel-node biopsy (SNB), and one after SNB. From the patients* perspective, additional time required is limited to 30 minutes per MRI session, including scanning, patient preparation, changing of clothes etc. The scan sessions are scheduled on the same day as the corresponding routine consultations for the RT planning procedure. Participants will lie in RT treatment position, i.e. supine with both arms in abduction, resting in an arm support. The ability to hold one*s arms in abduction during scanning is not expected to be a problem, although it can be affected after surgery. Therefore, coping ability is monitored for all patients. The study can lead to insights about the possible added value of using MRI techniques in regional RT planning for breast-cancer and/or DCIS patients in the future.

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

Female gender; >18 years old; breast-cancer patient or DCIS patient; if breast-cancer: stage T1-3 tumour, i.e. tumour of any size without direct extension to the skin; no pathologically enlarged lymph node(s) at clinical inspection (cN0), i.e. ultrasound and/or fine-needle aspiration; scheduled for sentinel-node biopsy; has given written informed consent

Exclusion criteria

Legal incapability; previous surgery of axillary and/or supraclavicular region; previous neo-adjuvant systemic treatment; adjuvant systemic therapy prior to radiotherapy course; immediate reconstruction of the breast after mastectomy; previously known inability to maintain the scanning position (supine with arms in abduction) for 30 minutes; MRI exclusion

criteria of the MRI safety group of Radiology (UMC Utrecht); not meeting the inclusion criteria

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):	20-02-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-12-2015
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	NL50046.041.14