The use of USPIO enhanced MRI in the assessment of axillary lymph node status in patients with invasive breast cancer

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

Summary

ID

NL-OMON30564

Source
ToetsingOnline

Brief title
The USPALS study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
lymph node metastasis, tumor positive lymph nodes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Breast cancer, lymph nodes, MRI, USPIO

Outcome measures

Primary outcome

The primary endpoint is the sensitivity of MRL for proved lymph node

involvement by histopathology on a patient to patient basis

Secondary outcome

· Sensitivity on a node to node basis

· Specificity, accuracy, negative predictive value and positive predictive

value on a patient to patient and node to node basis

· Posttest probability negative rate

· Feasibility of MRL after SLNB

· Diagnostic accuracy of MRL after SLNB

· Prognostic value of IMN involvement

· Prognostic value of positive and negative MRL after positive SLNB followed by

irradiation of the axilla

· Feasibility of MRL after neoadjuvant chemotherapy

· Diagnostic accuracy of MRL after neoadjuvant chemotherapy

· Effect of chemotherapy on tumor positive axillary lymph nodes

Study description

Background summary

The prognosis of invasive breast cancer is reduced in patients with axillary lymph node metastases. Staging of the axilla is nowadays performed by a

sentinel lymph node biopsy (SLNB). A positive SLNB is followed by axillary lymph node dissection (ALND), a negative SLNB requires no further surgery. ALND is an invasive procedure with severe morbidity in 10-20% of patients. Recent evaluation of a new intravenous MR contrast agent (Ultrasmall, SuperParamagnetic Iron Oxide nanoparticles, USPIO) has proved that lymph node metastases can be visualised accurately in a non-invasive way.

Study objective

Uspio enhanced MRI (MRL) potentially has the ability to show all lymph nodes and hence provide information on metastasis in all nodes, this is in contrast with SLNB which only provides information on 1 (or a few) lymph node(s). With MRL metastases down to a size of 1 mm are detected.
In 38% to 62% of patients with a positive sentinel lymph node (SLN), the SLN is the only positive node. ALND is performed in all these women and only afterwards judged unnecessary. We expect MRL to be able to identify, with a high negative predictive value, women who have no (further) involvement of lymph nodes prior to SLNB or after a positive SLNB. Consequently ALND can be withheld from these women. This saves morbidity and costs associated with ALND. MRL may also prove valuable in the 4% of patients where localisation of the SLN fails. All of these patients are now subjected to ALND. Use of MRL may prevent this. Finally, because SLNB is false negative in 7-9% of patients, some patients are inadequately treated. MRL has a high sensitivity and provides information on all lymph nodes, consequently it may reduce the number of false negative SLNB findings.

Study design

In patients with invasive breast cancer an USPIO enhanced MRI (MRL) will be made prior to any surgical procedure to the axilla. The performance of MRL will be controlled by ex vivo MRL of all surgical specimen, followed by a node-to-node matching of all imaged nodes with pathology. Pathologic examination of excised nodes will be regarded as the gold standard for evaluation of node involvement. When the MRL is positive, but the SLNB is negative no surgery will be performed but an image guided biopsy of affected node(s) will be done and the pathologic examination of this biopsy will be used as reference value.

Study burden and risks

Patients need to be at the hospital for administration of the contrast agent. This will take approximately 30 minutes. Patients may complain of pain (usually in the back) due to the administration of the contrast agent. Reduction of the administration speed usually resolves this problem. There is also a minor risk for allergic reactions and in a few cases anaphylactic reactions have been described. Therefore medical observation is needed and will be performed during

1 hour after administration. This ensures adequate medical treatment in case of emergencies.
Furthermore the MRI itself needs to be made. This requires the patient to be at least 40 minutes inside the MRI-scanner. Although this is harmless, it may be experienced as a burden, especially by people with mild claustrophobia. (Severe claustrophobia is an absolute contra-indication).

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

- Histologically proven invasive breast cancer
- Surgical removal of at least 1 axillary lymph node will be performed
- Patient must be accessible for treatment

- Patient must provide written informed consent

Exclusion criteria

- Patient age < 18
- Karnofsky score = 70 or <70
- Pregnant or lactating women
- Patients with conta-indications for MRI scanning (e.g. pacemaker, claustrophobia, ferromagnetic objects in the eyes or brain)
- Patients with contra-indications for the use of USPIO based contrast agents or dextran (e.g. known allergy)
- Male gender

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2007
Enrollment:	440
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	sinerem
Generic name:	ferumoxtran-10

Ethics review

Approved WMO Date:	18-12-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2006-006181-42-NL
CCMO	NL14826.091.06