Radiation-free, magnetic, sentinel lymph node detection and evaluation

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON27580

Source
NTR

Brief title
LowMag

Health condition

Breast cancer, borstkanker
Results are also applicable to melanoma, prostate cancer.
Resultaten zijn ook toepasbaar op melanoom en prostaatkanker.

Sponsors and support

Primary sponsor: University of Twente, Enschede, the Netherlands
Source(s) of monetary or material Support: STW (Stichting Technologische Wetenschappen), initiatior and participant (Medisch Spectrum Twente)

Intervention

Outcome measures

Primary outcome

1. The proportion of sentinel nodes correctly detected with the magnetic method compared to the combined technique (visually and/or using the gammaprobe).

2. The proportion of patients in which the sentinel lymph nodes could successfully be detected (detection rate) using the magnetometer.

3. The number and percentage of sentinel lymph nodes correctly diagnosed to be metastatic using ex vivo MRI „³ sensitivity;

4. The number and percentage of sentinel lymph nodes correctly diagnosed to be non-metastatic using ex vivo MRI specificity.

Secondary outcome

5. The iron content in the dissected sentinel lymph nodes (average, minimum and maximum) in relation to the image quality;

6. The image parameters indicative for the presence of sentinel lymph node metastases;

7. The requirements in detection depth and minimally detectable mg iron per node for future magnetometers;

8. The usability of a dose of 1.1 mg iron in 1 ml injected volume for the proposed study.

Study description

Study objective

The sentinel lymph nodes (SLN) are the first lymph nodes to drain the tumor site and therefore the first lymph nodes to bare metastases. Hence the importance to investigate these lymph nodes to define the best treatment strategy. Currently in a.o. breast cancer and melanoma patients, the sentinel lymph nodes are intraoperatively detected, both visually and by using a gamma probe, following the subsequent injections of radioactive tracer (Tc 99-m) and blue dye (Patent Blue). Histopathological investigation of the resected sentinel lymph nodes should then confirm the presence or absence of metastases. The conventional methods for sentinel lymph node biopsy suffer from disadvantages, such as the use of radioactive materials and the fact that node-positive patients require multiple surgical procedures. At the NeuroImaging (NIM) group of the University of Twente, we investigate a magnetic, radiation-free, procedure for sentinel lymph node detection and evaluation. Several aspects of this procedure have been investigated in separate studies. Though results were promising, showing a detection rate of the sentinel node non-inferior to the existing technique and proving the feasibility to visualize the sentinel node in preoperative MRI, the doses and volume of the injected magnetic tracer (SuperParamagnetic Iron Oxide particles, SPIO), were relatively high. The high dose of iron potentially leads to difficulties in evaluating lymph nodes with small metastases and to substantial skin staining. Additionally, the high volume of injected tracer might in some cases lead to a non-physiological uptake of iron in the lymph vessels, reducing the reliability for detecting (solely) sentinel lymph nodes. In this

study, the aim is to investigate the feasibility of using low dose SPIO (50x lower than the previously safely used dose) for both evaluation and detection of the sentinel lymph node in breast cancer patients.

Study design

The study outcomes will be evaluated after every ten successful measurements, after every 5 MRI investigations on specimen containing macrometastases, after every 5 MRI investigations on specimen not containing metastases and at the end of the study.

Intervention

A low dose peritumoral injection of Sienna+ (2x 0.5 mL), with a total dose of approximately 1.1 mg iron.

Contacts

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Eligibility criteria

Inclusion criteria

Adult, clinically (palpation and ultrasound) node negative, patients that are diagnosed with invasive breast cancer or high grade ductal carcinoma in situ and that are scheduled for a two-day SLNB procedure and that gave informed consent for participation to the study;

Exclusion criteria

1.Patients incapable of giving informed consent for participation to the study;

2.Intolerance / hypersensitivity to iron or dextran compounds;

3.Patients that have received neoadjuvant chemotherapy in the period of 5 years prior to this study.

4.Pregnant or lactating patients

5.Patients having a pacemaker implanted.

Study design

Design

Intervention model: Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-11-2014
Application type:	First submission

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
NTR-new	NL4698
NTR-old	NTR4903
Other	NL49285.044.14 : METC Twene P14-32

Study results