Low dose SPIO injection for a complete magnetic, radiation-free, procedure for sentinel lymph node detection and metastases evaluation.

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To investigate the possibility of using low dose peri-tumoral Magtrace® injection for a complete magnetic, radiation free, procedure for sentinel lymph node (SLN) detection and evaluation. This objective, can be sub-divided in the following...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON56058

Source
ToetsingOnline

Brief title
Low dose magnetic sentinel lymph node detection and evaluation

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Dit onderzoek valt binnen een project dat is gesubsidieerd door de Stichting Technologische Wetenschappen (STW);onder nummer STW NIG 10891

Intervention

Keyword: breast cancer, magnetic, radiation-free, Sentinel node

Outcome measures

Primary outcome

1. The proportion of sentinel nodes correctly detected with the magnetic technique (magnetometer)

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.

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

5. The uptake of SPIO particles in normal breast tissue versus tumor tissue.

6. The number and percentage of sentinel lymph nodes correctly diagnosed to be metastatic using in vivo MRI.

7. The number and percentage of sentinel lymph nodes correctly diagnosed to be non-metastatic using in vivo MRI.

Secondary outcome

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

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

10. The requirements in detection depth and minimally detectable mg iron per

node for future magnetometers.

Study description

Background summary

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, the sentinel lymph node procedure is performed using a magnetic tracer and detection probe. Histopathological investigation of the resected sentinel lymph nodes should then confirm the presence or absence of metastases. However, In 80% of patients, the nodes are healthy. At the Magnetic Detection & Imaging group of the University of Twente, we investigate a magnetic, radiation-free, procedure for sentinel lymph node detection and evaluation.
In this study, the aim is to investigate the feasibility of a low-dose SPIO injection for both evaluation and detection of the thyroid gland in breast cancer patients. If we can compare MRI images of the lymph nodes with the pathology images, we may be able to determine the patient's node status using MRI in the future. In 80% of patients with clean lymph nodes, an SLNB operation can then possibly be avoided.

Study objective

To investigate the possibility of using low dose peri-tumoral Magtrace® injection for a complete magnetic, radiation free, procedure for sentinel lymph node (SLN) detection and evaluation.
This objective, can be sub-divided in the following objectives:
1) To test the intraoperative detectability of the SLN using low dose Magtrace® in combination with the SentiMag® system. (regular care)
2) To ex vivo test the best MR imaging sequence for visualization of the SLN and the detection of SLN metastases in SPIO (Sienna+®)-containing nodes.
3) To ex vivo evaluate the possibility of SPIO(Sienna+® or Magtrace®)-enhanced metastases detection.
4) To translate results to an in vivo imaging study and protocol.
5) To relate the (semi-quantitative) amount of iron in the excised lymph nodes to the intraoperative performance of the first and second generation magnetometers, specifically for the low-dose peritumoral Sienna+® or Magtrace® injection.

Study design

Experimental, minimally invasive, pilot study in breast cancer patients.

Intervention

Optional in vivo MRI. and ex vivo MRI of the lymph nodes

Study burden and risks

This research will not be beneficial to the subject. However, the results of the study will be used to optimize the detection procedure for the sentinel lymph node as well as the diagnosis of sentinel lymph node metastases. The study outcomes are used to progress to a radiation-free and minimally invasive procedure. The benefits are concerning the future patient group, including not only breast cancer patients, but also melanoma patients and potentially all solid cancers eligible for SLNB. The information obtained in this study can also be used in related procedures in colorectal cancer patients. The study won*t delay diagnosis and won't significantly delay treatment, it won*t cost extra time for the patient or surgeon and the patient is not subjected to any acts. The possible delay of the surgergical date will be in the order of days and the time between surgery and treatment will always be according to the national guidelines. The only burden is the optional MRI examination. The patient will not experience any side effects from the two in-vivo MRI scans in this study. Prior to MRI, patients follow the standard questionnaire that applies to all other MRI examinations in the MST. With the questionnaire will be determined if the patient is suitable for the MRI examinations.
The ex-vivo MRI of the lymph nodes and pathological examination of the lymph nodes takes place outside the presence of the patient himself. So they do not experience any burden as a result.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Adult patients with breast cancer scheduled for a SLNB procedure or axillary dissection and have at maximum clinically (palpation and ultrasound) N+, 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.Pregnant or lactating pratients
4.Patients having a pacemaker implanted.

Exclusion criteria as long as the post-surgery MRI is obligated
Patients scheduled for a lumpectomy and who are not eligible for MRI according to the MRI exclusion criteria of MST.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2016
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Injection of Sienna+ or Magtrace;detection with SentiMag (Magnetometer)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-12-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-08-2019

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-08-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-09-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL49285.044.14