Magnetic marker localisation for non-palpable breast cancer.

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The primary objective of this study is to determine the competence of a magnetic marker as a technique to localise non-palpable breast cancer, measured through retrieval rate using only the magnetic probe. The secondary objectives of this study are...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON48788

Source
ToetsingOnline

Brief title
Magnetic marker localisation

Condition

- Miscellaneous and site unspecified neoplasms benign
- Breast therapeutic procedures

Synonym
Breast cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Breast conserving surgery, Magnetic localisation, Non-palpable breast cancer

Outcome measures

Primary outcome

Data regarding the retrieval rate of the magnetic marker will be collected peri-operatively, using the magnetic probe to confirm the marker present in the excised tissue and to confirm the marker absent in the patients. Postoperatively, a pathologist will confirm the presence of the marker in the excised tissue.

Secondary outcome

Data regarding the resection margins will be collected from the pathology report.

Data with respect to radiologist and surgeon satisfaction will be measured through the questionnaires presented in appendix 2.

During the intake session, before the radiological intervention, patient demographics and relevant medical data will be registered, regarding the age of the patient, the location of the tumour (left or right breast, quadrant of the breast), histological aspects of the tumour (type, grade, size) and time between marker placement and surgery.

Study description

Background summary

When conducting breast-conserving surgery, accurate tumour localisation is challenging when the tumour is not palpable. Existing techniques for tumour localisation, such as wire guided and radioactive seed localisation yield acceptable results but have considerable disadvantages, like organisational and legislative aspects and high patient discomfort. Recently, a new technique has been developed to overcome these issues; localisation through a magnetic marker and probe.

Study objective

The primary objective of this study is to determine the competence of a magnetic marker as a technique to localise non-palpable breast cancer, measured through retrieval rate using only the magnetic probe. The secondary objectives of this study are (I) to assess the resection margins and (II) to assess radiologist and surgeon satisfaction.

Study design

A prospective cohort pilot study.

Intervention

Radiological intervention
All patients will receive a radioactive iodine seed (Bard Medical, Covington, USA) as per standard care, and the experimental magnetic marker (Magseed marker, Sysmex Europe GmbH). A radiologist will implant both markers under ultrasonic guidance in the same session. After implantation, the accuracy of location will be assessed through mammography.

Surgical intervention
The surgery will be performed within 30 days of implantation. During the surgery, the magnetic probe (Sentimag Probe, Sysmex Europe GmbH) will be available for localising the marker. Polymer tools will be provided as to not interfere with the magnetic probe. The gamma probe (Neoprobe, Mammotome, Cincinnati, USA) will be available, however, it will only be used as a back-up for when localisation through the magnetic probe is not possible or when the surgeon feels unsure about the location determined with the magnetic probe. Post-operatively, patients will receive standard follow-up care.

Study burden and risks

Implanting one extra marker in addition to the standard care marker, implanted through the same incision, without extra time or risk for the patient.

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

I. Female patients aged 18 years or older;
II. Patients have biopsy-confirmed, unifocal, non-palpable breast cancer;
III. Patients are eligible for breast-conserving surgery;
IV. Patients did not undergo any neo-adjuvant treatment;

Exclusion criteria

Patients do not have a pacemaker.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-10-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Magseed magnetic marker
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-04-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL65259.058.18