Magnetic marker localization for non-palpable breast cancer

No registrations found.

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

Summary

ID

NL-OMON23325

Source
Nationaal Trial Register

Brief title
MAG10

Health condition

Breast Cancer

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcome measure is retrieval rate of the magnetic marker using only the magnetic probe.

Secondary outcome

Secondary outcome measures are resection margins, collected from pathology reports and radiologist and surgeon satisfaction, determined through questionnaires.

Study description

Background summary

Rationale: When conducting breast-conserving surgery, accurate tumor localization is challenging when the tumor is not palpable. Existing techniques for tumor localization, such as wire guided and radioactive seed localization yield acceptable results but have considerable disadvantages, like organizational and legislative aspects and high patient discomfort. Recently, a new technique has been developed to overcome these issues; localization through a magnetic marker and probe.
Objective: To test feasibility of magnetic marker localization as a technique to operate on non-palpable breast cancer and to determine radiologist and surgeon satisfaction.
Study design: A prospective cohort pilot study.
Study population: 10 women, aged 18 years or older, with non-palpable, biopsy confirmed, unifocal breast cancer eligible for breast-conserving surgery that have not undergone any neo-adjuvant treatment.
Intervention: A radiologist will first implant a magnetic marker and then a radioactive marker using image guidance. During surgery, the surgeon will locate the tumor using the magnetic probe and only use the gamma probe when it is deemed irresponsible to continue with the magnetic probe.
Main study parameters/endpoints: The primary outcome measure is retrieval rate of the magnetic marker using only the magnetic probe. Secondary outcome measures are radiologist and surgeon satisfaction, determined through questionnaires and resection margins, collected from pathology reports.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Implanting one extra marker in addition to the standard care marker, implanted through the same incision, without extra risks or hospital visits for the patient.

Study objective

The magnetic marker is comparable to the I-125 marker regarding retrieval rate

Study design

4

Intervention

All patients will receive a radioactive iodine seed (Bard Medical, Covington, USA) as per standard care, and the magnetic marker (Magseed, Endomag, Cambridge, UK). A radiologist will first implant the magnetic marker to ensure optimal placement and will then implant the

iodine seed. Both markers will be placed under ultrasonic guidance and in the same session. After implantation, the accuracy of location will be assessed through mammography.
The surgery will be performed within 30 days of implantation. During the surgery, the magnetic probe (Sentimag probe, Endomag, Cambridge, UK) will be available for localizing 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 localization through the magnetic probe is not possible or when the surgeon feels unsure about the location determined with the magnetic probe. Once the lesion is resected, the gamma probe will be used to confirm the presence of the iodine seed in the resected tissue. Post-operatively, patients will receive standard follow-up care.

Contacts

Public
Leids Universitair Medisch Centrum
Iris Noordhoek

+31715264576
Scientific
Leids Universitair Medisch Centrum
Iris Noordhoek

+31715264576

Eligibility criteria

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;
V. Patients are willing and able to provide written informed consent.

Exclusion criteria

I. The patient has a pacemaker.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-07-2019
Enrollment:	10
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-07-2019
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	NL7881
Other	CME LUMC : P19.016

Study results