

MaMaLoc: A study on the use of a magnetic marker for tumor localization in breast cancer surgery.

No registrations found.

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

Summary

ID

NL-OMON23005

Source

NTR

Brief title

MaMaLoc-2

Health condition

mamma carcinoma, tumor localization, usability, patient outcome, innovation

borstkanker, tumorlokalisatie, gebruiksgemak, patientuitkomsten, innovatie

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek, NKI

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Surgical usability, (defined as the general System Usability Scale (SUS))

Secondary outcome

- Surgical convenience (questionnaire and RTA)
- Radiologist satisfaction (SUS)
- Patient reported pain (VAS)
- Patient convenience of the technique (Likert scale)
- Clinical parameters
- Success rate of localization procedure
- Resection margin status
- Operation time
- Re-operation rate
- Specimen weight and volume
- Marker migration (intervention group subset, max N=10)
- Learning curve for the MaMaLoc localization technique.

Study description

Background summary

Rationale: All currently available tumour localization technologies for non-palpable breast lesions suffer from significant disadvantages, ranging from poor accuracy (wire-guided localization, WGL), low uptake due to the laborious nature of implementing the technique (radioactive techniques) to time consuming (ultrasound guided). There is a clear demand for a novel, accurate but non-radioisotope based localization technique.

Objective: To investigate surgical and radiological usability, patient-reported outcome measures, and effectiveness of the MaMaLoc technique: a novel magnetic localization technique for intra-operative breast lesion localization, compared to standard wire-guided localization (WGL).

Study design: Pilot randomized controlled study, two groups: conventional localization technique WGL (control group) and MaMaLoc (interventional group)

Study population: All non-pregnant breast cancer patients aged ≥ 18 years, with a unifocal

tumour, with good ultrasound visibility, scheduled for breast conserving surgery with localization in the Franciscus Vlietland hospital and not meeting any of the exclusion criteria.

Intervention: Subjects will be allocated randomly to either WGL (control group) or MaMaLoc (interventional group) by drawing an envelope.

Main study parameter: Primary endpoints: Ease of use surgeon (System Usability Scale (SUS)). Secondary endpoints: Surgeon Satisfaction, Radiologist satisfaction (SUS, convenience), Patient reported pain (Visual Analog Scale, VAS) and convenience of technique (Likert scale 1-5), success percentage, resection margin status, re-operation rate, operation time, volume of resected specimen, learning curve.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patient burden of the interventional group compared to the standard of care (WGL) is similar. Placement of a wire (WGL) is replaced by placement of a magnetic marker (MaMaLoc). Patient risk is minimal. Detection using low-field magnetism is inherently safe and the marker is constructed from biocompatible materials. In vivo research in fifteen patients has already shown safety and feasibility of the technique. Participation for the patient implies the addition of 2 very short questionnaires, hence additional patient burden is low. This study on breast lesion localization can only be done in this patient population.

Study objective

We hypothesize that the MaMaLoc localization technique is superior compared to wire guided localization in terms of surgical ease of use, measured as the System Usability Scale (SUS) score.

Study design

T0 inclusion

T1 marker/wire placement with X-ray confirmation

T2 surgery

T3 pathological assessment

Intervention

Subjects will be allocated randomly to either WGL (control group) or MaMaLoc (interventional group) by drawing an envelope.

In the interventional treatment group (N=35), localization is performed using magnetic localization: the MaMaLoc technique. With this technique, the radiologist places a magnetic marker in the tumour up to 30 days prior to surgery, using ultrasound guidance. . A two-way mammography is obtained directly subsequently to confirm correct placement of the marker.

For a subset of patients (max N=10) in the interventional group in which a biopsy site marker or other localisation marker (such as o-ring, twist-maker) was already in situ, at the day of surgery, patients will be asked to undergo an extra mammography to assess marker migration and ensure continued proper localization of the experimental marker. The other localisation marker is used as reference in both post-placement and pre-surgery images.

During surgery, a commercially available magnetic detector (Endomag Sentimag) is used to accurately detect the marker, and guide surgery. During measuring at the OR, polymer surgical instruments are used to prevent disrupting the magnetic detector signal (B Braun Aesculaep SUSI instruments). If the technology is insufficient in guiding the surgeon, he or she may opt to fall back to ultrasound guided surgery.

In the standard treatment group (N = 35), subjects receive the wire guided localization technique. In wire guided localization, a radiologist places a metal wire with an anchor tip in or near the tumour using ultrasound guidance, prior to surgery (at maximum one day in advance). A two-way mammography is obtained directly subsequently to confirm correct placement of the wire (tip). During the subsequent surgery, the surgeon follows the wire and resects the tissue around the tip including the wire.

Contacts

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Eligibility criteria

Inclusion criteria

breast cancer patients

aged ≥ 18 years

unifocal tumour

good ultrasound visibility

scheduled for breast conserving surgery with localization

Exclusion criteria

Patients scheduled for an MRI scan in the period between marker placement and surgery

(Expected) time between placement of magnetic marker and surgery > 30 day

Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	23-10-2017
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date: 20-10-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44563

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6553
NTR-old	NTR6767
CCMO	NL62033.101.17
OMON	NL-OMON44563

Study results