Magnetic Marker Localization for breast cancer surgery: An exploratory study

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The purpose of this clinical study is to investigate surgical usability, patient-reported outcomes and effectiveness of the MaMaLoc technique and compare it with WGL.

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

Summary

ID

NL-OMON44563

Source
ToetsingOnline

Brief title
MaMaLoc-2

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast-Conserving Surgery, magnetism, tumor localization, usability

Outcome measures

Primary outcome

Ease of use surgeon (System Usability Scale)

Secondary outcome

* Radiologist satisfaction (SUS) * Retrospective think aloud for surgeon and radiologist after procedure * Tumor-depth on ultrasound and mammography, in mm (skin to lesion) * Surgeon convenience (specific questionnaire) * Operative time in minutes * Delay in OR sheculding/start as a consequence of the localization technology (in minutes) * Intervention only: learning curve assessment * Intervention only: marker migration * Success percentage: no fall-back to ultrasound needed * Specimen weight (g), size (mm), volume (cc) * Dominant tumor size (in mm) * Resection margin status * Histopathological data * Patient reported pain (VAS) * Patien reported convenience (likert)

Study description

Background summary

All currently available tumor localization techniques for non-palpable tumors during breast conserving surgery have obvious drawbacks. Wire-guided localization has a low accuracy, is painful and comes with challenging logistics. Radioactive alternatives such as radioactive seed localization (RSL) or Radioactive Occult Lesion Localization (ROLL) were limited implemented in daily practive clinic because of strict regulations and protocol requirements that come with the implementation of a new radioactive technique. Also, ultrasound-guided localization during the surgery has the disadvantage that it is challenging due to the required presence of a radiologist, or a trained surgeon, which is time-consuming and bears logistic challenges. Three quarters

of patients are still treated with a suboptimal technique, therefore, the development of new techniques is imperative. Our group started to investigate the use of magnetism for tumor localization, analogue to RSL. A new, radiopaque, magnetic marker was developed, which can be implanted in the tumor up to 30 days before surgery. This marker can be accurately detected during the operation by using a commercially available portable magnetic probe which functions as a gamma probe. The advantage of using magnetism is the omission of the use of radioactive material and the accompanied regulations and protocol requirements. Also magnetism does not decay over time. In previous studies, the magnetic marker and detection characteristics have been developed and validated in a laboratory environment, and proof-of-principle was obtained in ex vivo animal and human tissues. A study in15 breast cancer patients demonstrated that this technique is feasible and safe, and that further research is fully warranted. Up till now, the experimental MaMaLoc technology was combined with a "fall-back" localization method (radioactive seed localization). Now with the demonstrated feasibility and safety, the magnetic localization technique will be investigated as sole localization technique. The purpose of this study is to investigate surgical usability, patient-reported outcomes and efficacy of the experimental magnetic technieque and to compare it with the worldwide gold standard (wire-guided localization) in a larger pilot study. The data collected in this study will be used to adequately power a randomized controlled trial .

Study objective

The purpose of this clinical study is to investigate surgical usability, patient-reported outcomes and effectiveness of the MaMaLoc technique and compare it with WGL.

Study design

Pilot prospective cohort study

Intervention

Subjects will be randomly assigned to either the first (control) or second (intervention) group by means of drawing an envelope. Wire Guided Localization is the current standard of care. With the MaMaLoc technique the magnetic seed is implanted in or near the breast lesion by the radiologist, after local anesthesia. During surgery the seed will be detected with a magnetic detector. After surgery, it will be confirmed that the magnetic seed is removed with the detector, as well as during pathology analysis. The further process is identical to standard care.

Study burden and risks

Burden for patients is similar in the intervention group compared to the

standard of care (WGL). Placement of a wire (WGL) is replaced by placement of a magnetic marker (MaMaLoc). The only additional burden for all participants is to fill out a questionnaire on two occasions: around the localization process and after surgery. This takes about 10 minutes in total. Patients risks are minimal. Eligible patients in the intervention group that already have a separate biopsy site marker in situ to use as a reference (max N=10) will undergo one extra mammography to assess MaMaloc marker migration (0.2 mSv total dose). Detection using low field magnetism is inherently safe and the marker is constructed from biocompatible materials. In vivo studies in fifteen patients have already demonstrated the safety and feasibility of the technique. The benefits of this research definitely outweigh the burden/risks for patients .

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

*breast cancer patient
*scheduled for breast conserving surgery with localization
*aged >=18 years
*unifocal tumor
*good ultrasound visibility

Exclusion criteria

* Planned MRI 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2017
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	MaMaLoc Marker and Applicator
Registration:	No

Ethics review

Approved WMO Date:	18-07-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-08-2018
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

ID: 23005
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62033.101.17
OMON	NL-OMON23005