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

Gepubliceerd: 20-10-2017 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23005

Bron
NTR

Verkorte titel
MaMaLoc-2

Aandoening

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

borstkanker, tumorlokalisatie, gebruiksgemak, patientuitkomsten, innovatie

Ondersteuning

Primaire sponsor: Antoni van Leeuwenhoek, NKI
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T0 inclusion

T1 marker/wire placement with X-ray confirmation

T2 surgery

T3 pathological assessment

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

breast cancer patients

aged ≥18 years

unifocal tumour

good ultrasound visibility

scheduled for breast conserving surgery with localization

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	23-10-2017
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-10-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44563
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten