MaMaLoc: Magnetic Marker Localisation for non-palpable breast lesions. A Feasibility Study.

Published: 30-11-2015
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To assess the clinical safety and feasibility of the MaMaLoc technique: a novel magnetic localisation technique for intra-operative lesion localisation.

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

Summary

ID

NL-OMON42528

Source
ToetsingOnline

Brief title
MaMaLoc Feasibility

Condition

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

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Localization, Tumor Localization

Outcome measures

Primary outcome

Identification rate (IR) of the magnetic marker relative to the total amount of

included subjects (percentage).

Secondary outcome

Not applicable.

Study description

Background summary

All currently available tumour localisation techniques for non-palpable breast lesions suffer from significant disadvantages, ranging from poor accuracy (wire-guided localisation) to low uptake due to the laborious nature of implementing the technique (radioactive techniques).

Study objective

To assess the clinical safety and feasibility of the MaMaLoc technique: a novel magnetic localisation technique for intra-operative lesion localisation.

Study design

The proposed study is designed as a non-blinded, non-controlled, observational phase I study in which we assess the feasibility of a novel magnetic medical device for the localisation of non-palpable breast lesions.

Intervention

The magnetic MaMaLoc marker is placed in or near the lesion by a radiologist, in an already locally anesthesized area during the same session as placement of the iodine seed. Directly prior to the start of the surgeon, a magnetic detector is used to locate the magnetic marker. After the surgery, the marker is confirmed present in the excised tissue using the magnetic detector as well

as the pathologist. The rest of the care process is identical to a 'standard' iodine seed surgery.

Study burden and risks

Patient burden is limited to one extra injection at the radiology department during a session that is conventionally used to implant a radio-active marker. Patient risk is negligible. Detection using low-field magnetism is inherently safe and the marker is constructed from biocompatible materials.

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

* Unifocal, non-palpable breast lesion
* Treated with breast sparing surgery
* Using radio-active seed localisation (RSL)
* Age > 18 years.

Exclusion criteria

* Treated with neo-adjuvant chemotherapy
* Planned MRI in the period between marker placement and surgery
* Tumor depth >4cm

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2016
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	MaMaLoc Marker
Registration:	No

Ethics review

Approved WMO

Date:	30-11-2015

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL53399.031.15

Study results

Date completed:	09-08-2016
Actual enrolment:	15