

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Breast neoplasms malignant and unspecified (incl nipple)
<b>Study type</b>	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 anesthetized 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**

### **Public**

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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