Evaluating the use of Magnetic Resonance Imaging and Contrast Enhanced Mammography after MagTrace® use

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The primary objective in this trial is to evaluate the use of MRI and contrast enhanced mammography after using MagTrace® to perform a breast conserving surgery and a sentinel node biopsy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON51366

Source
ToetsingOnline

Brief title
MagTrace 2

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Zuyderland/Borstcentrum

Intervention

Keyword: Breast cancer, Contrast enhance mammography, MagTrace, MRI

Outcome measures

Primary outcome

To evaluate the use of MRI and CEM, the following primary endpoints will be assessed: Visibility and size of artefacts undergoing MRI and CEM and its consequences of the quality for image assessment.

Secondary outcome

n/a.

Study description

Background summary

MagSeed® and MagTrace® will be implemented as standard of care for breast conserving surgery and sentinel lymph node biopsy, since it has several advantages compared to a radioactive technique. However, MagTrace® is known to interfere with MRI during follow-up imaging when using 2 mL. No data is available for patients who received 1 mL of MagTrace®, as is described in our current protocol. A contrast enhanced mammography (CEM) could be an alternative for MRI if it still shows artefacts.

Study objective

The primary objective in this trial is to evaluate the use of MRI and contrast enhanced mammography after using MagTrace® to perform a breast conserving surgery and a sentinel node biopsy.

Study design

Prospective trial in an outpatient clinic setting.

Study burden and risks

Since MagTrace® and MagSeed® will be implemented as standard localisation technique for breast conserving surgery and sentinel lymph node biopsy in Zuyderland MC, the information obtained from this trial is essential for the follow-up planning of all breast cancer patients. Therefore, the burden for the patients (undergoing extra imaging) will be in proportion to the added value of this trial.

Contacts

Public
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Geleen 6162 BG
NL
Scientific
Zuyderland Medisch Centrum

Dr. H. van der Hoffplein 1
Geleen 6162 BG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female patients of 18 years and older.
- Previously underwent breast conserving surgery and sentinel lymph node biopsy using MagTrace®.

- Undergoing standard follow-up for previous breast cancer

Exclusion criteria

- Unable to comprehend the extend and implications of the study and sign for informed consent.
- Standard MRI exclusion criteria:
o Implantable (electrical) devices (e.g., pacemaker, cochlear implants, neurostimulator);
o Any other metal implants;
o Claustrophobia;
o MR-incompatible prosthetic heart valves.
- Standard CEM exclusion criteria:
o Breast implants.
NB: since no contrast will be used during the CEM, standard contrast contraindications were not included as exclusion criteria for this trial.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2022
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-09-2022

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL82061.096.22