Magnetic tracer in the sentinel node procedure in breast cancer: the non-radioactive alternative for radio-isotopes

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The primary objective of this study is to analyse the feasibility and internal validity of Magtrace in the sentinel node procedure in breast cancer in the Breast Care Centre in Zuyderland Medical Centre; with the ultimate goal to make the sentinel...

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

Summary

ID

NL-OMON49099

Source
ToetsingOnline

Brief title
MagTrace

Condition

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

Synonym
sentinel node procedure

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: magnetic tracer, sentinel node procedure

Outcome measures

Primary outcome

To assess

1. The concordance in detection of sentinel nodes by Magtrace and the

Technetium tracer.

Secondary outcome

1. Operation time sentinel node procedure

Study description

Background summary

In breast cancer, a sentinel node procedure is performed to investigate whether malignant cells have spread to the axillary lymph nodes. This is an important part of determining the stage of breast cancer and the final treatment plan.
In current practice the lymph nodes are localized with the radio-isotope Technetium (in combination with a blue dye). Due to the half-life of Technetium, the nuclear medicine physician usually injects this tracer one day preoperatively. Subsequently a nuclear scan is made to evaluate the route of the tracer. In the operation theatre the surgeon will detect the radioactive Technetium signal with a gamma-probe. A concomitant blue dye can be used for visual detection of the sentinel nodes.
Magtrace is an alternative for Technetium. It consists out of iron oxide nanoparticles, covered in a carboxydextran coating. After injection, it spreads to the lymph vessels and the sentinel node, just as Technetium.
With the Sentimag-probe the sentinel nodes can be magnetically localized. The brown colour of the Magtrace will cause a concomitant visual marking. In contrast to Technetium, with Magtrace no preoperative nuclear scan is required one day preoperatively. Nor is concomitant injection of blue dye necessary.
A disadvantage of the sentinel node procedure with Technetium is that it is performed using radioactive tracing with concomitant radiation exposure for the patients and all medical personnel involved. In addition, the use of radioactive tracing puts high demands on the logistics in the operation

theatre: the capacity of the number of patients that can be treated in one day is limited and the radio-active tracing leads to many time-consuming precautionary measures.
A radiation free alternative would therefore be advantageous. Not only with respect to radiation exposure for the patients and health care workers, but also by reducing the waiting time for operation for the patients, as it will make the planning of patients for operation more efficient.

This study aims to analyse the feasibility and internal validity of Magtrace in the sentinel node procedure in breast cancer; with the ultimate goal to make the sentinel node procedure a radiation free process.

Study objective

The primary objective of this study is to analyse the feasibility and internal validity of Magtrace in the sentinel node procedure in breast cancer in the Breast Care Centre in Zuyderland Medical Centre; with the ultimate goal to make the sentinel node procedure a radiation free process.

Study design

A prospective cohort of 40 patients with breast cancer and an indication for the sentinel node procedure will be injected with both Technetium (radioisotope) and Magtrace (magnetic). All patients in this study will receive both tracers.

Intervention

Intervention group

This is a prospective cohort of all patients with breast cancer and an indication for a sentinel node procedure. These patients will be injected with the magnetic tracer (Magtrace) and the Technetium tracer preoperatively. Perioperatively the sentinel node procedure will be performed using the Sentimag-probe to localize the Magtrace. The Technetium tracer will be used to check if the removed sentinel nodes are Technetium positive and with the gamma-probe it is checked if there are sentinel nodes in the axilla that were not detected by the Magtrace.

Study burden and risks

The goal of this project is proving the feasibility and internal validity of Magtrace in the sentinel node procedure. To establish that Magtrace is a non-inferior and a non-radioactive alternative for Technetium with respect to reliability in detecting metastases. The ultimate goal is to make the sentinel

node procedure a radiation free process.

Contacts

Public
Zuyderland Medisch Centrum

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

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

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Female patient of 18 years or older.
- Patient with breast cancer and indication for sentinel node procedure.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients with a previous history of the sentinel node procedure or axillary lymph node dissection in the ipsilateral breast.
- Hypersensitivity for ironoxide or dextran

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2021
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	08-06-2021
Application type:	Amendment
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	NL75877.096.20