Simplifying the sentinel node procedure in breast cancer using a portable gamma camera in order to replace conventional preoperative lymphatic mapping.

Published: 30-06-2017 Last updated: 11-04-2024

The primary objective is to evaluate the SN detection rate of the PGC in breast cancer compared to CGC imaging.

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

Summary

ID

NL-OMON45614

Source ToetsingOnline

Brief title SENTIMAP

Condition

• Breast neoplasms malignant and unspecified (incl nipple)

Synonym lymph node, Sentinel node

Research involving Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis **Source(s) of monetary or material Support:** Intern van afdeling Nucleaire Geneeskunde

1 - Simplifying the sentinel node procedure in breast cancer using a portable gamma ... 14-05-2025

Intervention

Keyword: Breast cancer, Lymphatic mapping, Portable gamma camera, Sentinel node

Outcome measures

Primary outcome

The main endpoint is the SN detection rate using the PGC in breast cancer compared to the current method, CGC imaging.

Secondary outcome

* Correlation of the SN detection rate with patients subgroups (tumor type,

T-stage, etc.)

* Utilization of the PGC by nuclear medicine technicians and breast surgeons

and the effects on logistics and work-flow at the department of Nuclear

Medicine;

* PGC SN detection rates correlated to PGC imaging acquisition times.

* PGC image quality compared to CGC image quality: SN visualization score (0=no

uptake, 1=weak, 2=moderate, 3=intense);

* A subjective descriptive analysis of the novel hybrid aspect of the PGC

where an optical image is combined with a scintigraphic image to combine

functional and anatomical information in a fused image output.

Study description

Background summary

The sentinel lymph node biopsy (SLNB) is a surgical procedure that can be used to stage the disease in breast cancer. The procedure includes a pathological examination of the first lymph node draining from the tumor, the sentinel node (SN). This node is visualized at the department of Nuclear Medicine and is

2 - Simplifying the sentinel node procedure in breast cancer using a portable gamma ... 14-05-2025

removed for pathological analysis during surgery. A radiotracer is administered in the breast and currently two imaging acquisitions are performed in order to visualize the SN: fifteen minutes and three hours after injection using a conventional gamma camera (CGC). Thereafter, the Nuclear Medicine physician reports the number of nodes and their location to the surgeon. The current imaging procedure at the department of Nuclear Medicine is time-consuming. A smaller, high-resolution portable gamma camera (PGC) is available that could simplify the imaging procedure. This may lead in clinical practice to substitution of the use of the CGC by use of PGC, provided it yields the same SN detection rate as the CGC.

Study objective

The primary objective is to evaluate the SN detection rate of the PGC in breast cancer compared to CGC imaging.

Study design

Single center prospective observational research

Study burden and risks

There are no immediate risks expected as a result of the additional imaging.

Contacts

Public Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121 Amsterdam 1066 CX NL Scientific Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121 Amsterdam 1066 CX NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Woman Proven primary breast cancer Scheduled for sentinel node procedure at the department of Nuclear Medicine Able to provide informed consent

Exclusion criteria

2nd primary in ipsilateral breast Breast cancer recurrence in ipsilateral breast DCIS and LCIS

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2017
Enrollment:	236

4 - Simplifying the sentinel node procedure in breast cancer using a portable gamma ... 14-05-2025

Type:

Actual

Ethics review	
Approved WMO Date:	30-06-2017
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 CCMO ID NL60147.031.16