Indocyanine green guided identification of sentinel lymph nodes via mastectomy incision in breast cancer patients.

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In this study, we aim to identify the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLNBs via the mastectomy incision.

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

Summary

ID

NL-OMON57105

Source
ToetsingOnline

Brief title
INIGMA study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds 2021 (Indirect) (¤71.073)

Intervention

Keyword: Breast cancer, Indocyanine Green, Mastectomy, Sentinel node

Outcome measures

Primary outcome

- To assess the detection rate of the ICG method to identify the SLN via a mastectomy incision.

Secondary outcome

- The detection rate of 99mTc.

- The difference in detection rate between ICG and 99mTc.

- The median number of SLN identified with ICG and the standard 99mTc.

- Percentage of SLNs that is fluorescent, but not positive for 99mTc.

- Percentage of SLNs that are not fluorescent but positive for 99mTc.

- The difference in pathology of the SLN found by ICG and 99mTc, including the difference between micro- and macro metastases (Mic and Mac resp.) and isolated tumor cells (ITCs).

- Detection time for the use of ICG to detect the SLN, defined as time between skin incision and SLN resection in minutes

- Complications, including wound infection, bleeding and lymphedema, of the combination of the ICG method and the standard 99mTc method to identify the SLN in mastectomies.

- The number of serious adverse events from the combination of ICG and 99mTc.

Study description

Background summary

Identifying lymphatic metastases is an important prognostic factor in the survival rate of breast cancer and the presence of lymphatic metastases carries consequences for further treatment. Results of our non-inferiority study (INFLUENCE study) and previous literature, led to the implementation of ICG-guided SLNBs via axillary incision as standard of care at St. Antonius Hospital and Isala Hospital (Zwolle). The applicability of ICG-fluorescence for SNLBs using the mastectomy incision has not been described yet. Surgeons may perform SLNBs using the same incision as the mastectomy, rather than using an additional axillary incision. In such setting, extended operating distance and visualization with an improper angle might introduce challenges to identify the SLN by tracking lymphatic vessels into the axilla.

Study objective

In this study, we aim to identify the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLNBs via the mastectomy incision.

Study design

This is a multicentre, cross-sectional study identifying the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping via the mastectomy incision (different surgical approach).

Intervention

All included patients will receive standard of care implying 99mTc injection the day before surgery. Consequently, 5 mg (2 ml) ICG will be injected periareolar after administration of general anaesthesia and before incision. The lateral edge of the standard mastectomy incision will be used to explore the axilla for ICG fluorescent lymph nodes to avoid a separate axillary incision. Then the excised nodes are tested for 99mTc activity with the standard gamma detecting probe as control. Lastly, the axilla will be explored with the standard gamma-probe for residual lymph nodes, and by common sight and palpation as a control.

Study burden and risks

Consenting patients will not need to do anything extra than the standard of care outside signing the informed consent. Administration of ICG will be done while under general anaesthesia, so patients will not experience extra discomfort, neither do they need extra site visits as the follow-up will be done during the standard follow-up appointment. ICG is safe to use: it is nonionizing and knows little to no complications and adverse events. Considering the cut-off of 2 additional nodes, the preferable topographic

location of these nodes and the clinical experience with additional lymph node sampling, we expect no increase in risk of surgical morbidity. Patients might benefit from the intervention as ICG can increase the identification rate of the sentinel lymph node procedure and might even replace 99mTc for SLN mapping. Thus, both risks and burden are minimal.

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

- Clinically node-negative, DCIS, invasive T1- T3 breast cancer confirmed by biopsy.
- Preoperative axillary ultrasound to confirm clinical node-negative status.
- Indication (or preference) for mastectomy and simultaneous SLN procedure.

- Written informed consent according to ICH/GCP and national regulations.

Exclusion criteria

- Patients < 18 years old
- SN-procedure via axillary incision
- Known allergy for indocyanine green (ICG), radioisotope technetium (99mTc), intravenous contrast, or iodine
- Other concurrent solid tumor.
- Hyperthyroidism or thyroid cancer
- Palliative surgery for locally advanced breast cancer (cT4)
- Pregnancy or breast feeding
- Psychological, familial, sociological or geographical factors that could potentially hamper compliance with the study protocol

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-08-2022
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2022
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-11-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-01-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80591.100.22