Identification of the sentinel lymph node in breast cancer patients through non-invasively fluorescent imaging using Indocyanine Green: an international multicenter implementation study.

Published: 21-02-2023
Last updated: 05-04-2024

The objective of this study is to evaluate the (nationwide and international) implementation of ICG-fluorescence for SN-procedures for patients with breast cancer.

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

Summary

ID

NL-OMON55958

Source
ToetsingOnline

Brief title
INFLUENCE II 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 2022

Intervention

Keyword: Breast cancer, ICG, Sentinel lymph node

Outcome measures

Primary outcome

To evaluate the effectiveness of Indocyanine Green (ICG) for sentinel lymph

biopsies in breast cancer patients.

Secondary outcome

Secondary Objectives:

To assess:

- The median number of SLN identified

- Percentage of SLNs that has 99mTc uptake/ is fluorescent

- The pathology of SLNs found by localization method, including micro- and

macro metastases and isolated tumor cells (ITCs)

- The detection time, defined as time between skin incision and SLN resection

in minutes

- Duration of the SN-procedure

- Duration of the total surgical procedure

- Complications, including seroma, wound infection and bleeding

- The number of serious adverse events

- Duration of the total procedure

- Locoregional recurrence after 1 year follow-up

To describe:

- (Pre-implementation) expectations regarding ICG

- (Post-implementation) experiences regarding ICG including success factors and

barriers.

- The process of the learning curve

To provide:

- National guidelines for ICG implementation

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. The golden standard for obtaining the SLN in patients with breast cancer is radioguided surgery with radioisotope technetium (99mTc). However, the use of 99mTc may present adverse effects and is logistical challenging. An alternative method is fluorescence imaging using Indocyanine Green (ICG).A recently published study (INFLUENCE trial) showed that ICG is a safe and effective method for SLN mapping in breast cancer patients with equal detection rates compared to Technetium.

Study objective

The objective of this study is to evaluate the (nationwide and international) implementation of ICG-fluorescence for SN-procedures for patients with breast cancer.

Study design

The INFLUENCE-II study is a (national and international) multicenter, prospective, pre-post implementation study describing the implementation of Indocyanine Green fluorescence imaging for SLN mapping in patients with breast cancer.

Intervention

Phase I (pre-implementation)

The standard of care SLN procedure will be performed, which implies 99mTc injection, the day or the morning before surgery. Study outcomes will be registered during SN-procedures. Questionnaires regarding ICG-related expectations will be collected.

Phase II (transition period)
In the transition period patients receive dual injection with both 99mTc-nanocolloid and ICG. Workshops and hands-on courses will be provided by initiating hospital. No study-related registrations during SN procedures in this phase are performed. Surgeons register the number of dual procedures needed to proceed to the use of ICG alone.

Phase III (post-implementation)
The SN-procedure is performed with the use of ICG as single tracer. Study outcomes will be registered during SN-procedures. Questionnaires regarding ICG-related experiences will be collected.

Study burden and risks

This study has no burden or risks for study participation

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 or invasive breast cancer confirmed by biopsy.
- Preoperative axillary ultrasound to confirm clinical node-negative status.
- Indication for SLN procedure via axillary excision
- Written informed consent according to ICH/GCP and national regulations.

Exclusion criteria

- Patients < 18 years old.
- SN-procedure via mastectomy incision
- Combined MARI procedure
- History of axillary lymph node dissection
- Known allergy for indocyanine green (ICG) or radioisotope technetium (99mTc) or intravenous contrast, iodine, shellfish.
- 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
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2023
Enrollment:	447
Type:	Actual

Ethics review

Approved WMO Date:	21-02-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	18-04-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	09-08-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	13-12-2023
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	NL79223.100.22