Identification of sentinel lymph nodes in breast cancer patients through non-invasively and percutaneously fluorescent imaging using ICG

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In this non-inferiority study, we aim to identify the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping versus the standard-of-care 99mTc in the SLN procedure for breast cancer patients.

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

Summary

ID

NL-OMON49864

Source
ToetsingOnline

Brief title
INFLUENCE-trial

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast carinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: St. Antonius Innovatiefonds 2018

Intervention

Keyword: breast cancer, icg, Sentinel lymph node

Outcome measures

Primary outcome

Identification rate of positive SLNs percutaneously by the fluorescent signal of ICG .

Secondary outcome

- Identification rate of positive SLNs percutaneously by 99mTc.
- Number of lymph nodes identified with ICG and standard 99mTc.
- Sensitivity: percentage of patients in whom fluorescent lymph nodes were identified of the total patients with identified sentinel lymph nodes by the standard 99mTc.
- False positive rates of ICG and 99mTc.
- False negative rates of ICG and 99mTc.
- Pathology of SLN found by ICG and 99mTc including micro- and macro metastasis and isolated tumor cells (ITCs).
- Intraoperative visualization of the SLN with the camera by ICG and 99mTc before skin incision.
- Transit time and detection time.
- Complications from ICG and 99mTc, including lymph edema, (wound)infection, bleeding.
- Number of adverse events from 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. The golden standard for obtaining the SLN in patients with breast cancer is radio guided surgery with radioisotope technetium (99mTc), sometimes combined with blue dye. However, both 99mTc and blue dye may present adverse effects and logistical challenges. A promising alternative method is the use of fluorescence imaging using indocyanine green (ICG). It is non-ionizing, easy to apply, patient- and surgeon friendly, safe, easy to obtain and cost-effective.

Study objective

In this non-inferiority study, we aim to identify the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping versus the standard-of-care 99mTc in the SLN procedure for breast cancer patients.

Study design

This is a single institution, single arm diagnostic efficacy trial identifying the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping versus the standard-of-care radioisotope technetium (99mTc) in the SLN procedure for breast cancer.

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. A surgically considered incision in the axilla is made while taking into account the marker of the ICG hotspots. 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, invasive early T1 or T2 breast cancer confirmed by biopsy.
- Preoperative axillary ultrasound to confirm clinical node-negative status.

- Indication for lumpectomy and SLN procedure.
- Written informed consent according to ICH/GCP and national regulations.

Exclusion criteria

- Patients < 18 years old.
- Mastectomy.
- 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

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-08-2020
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Fluobeam800 camera - Fluorescence imaging
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	NANOCOLL 0,5 mg

Generic name:	99mTc-albumin nanocolloid
Product type:	Medicine
Brand name:	VERDYE 25 mg
Generic name:	indocyanine green
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-01-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-02-2020
Application type:	First submission
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

ID: 29593
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-003828-21-NL
CCMO	NL71617.100.19

Study results

Date completed:	09-01-2022
Results posted:	01-08-2023
Actual enrolment:	102

First publication
01-08-2023