Evaluation of Indocyanine Green (ICG) enhanced Near-InfraRed Fluorescence (NIRF) Imaging for Intra-Operative Sentinel Lymph Node (SLN) detection in Breast Surgery.

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This study aims at evaluating whether indocyanin green (ICG) enhanced intra-operative near-infrared fluorescence (NIRF) imaging is as good as or even better than the standard technique (technetium-99 labeled colloid and Patent Blue) in detecting...

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-OMON33334

Source
ToetsingOnline

Brief title
Sentinel node detection with ICG enhanced NIRF optical imaging.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Therapeutic procedures and supportive care NEC

Synonym
breast cancer, sentinel lymph node procedure

Research involving
Human

Sponsors and support

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

Intervention

Keyword: breast cancer, fluorescence imaging, intraoperative, sentinel node

Outcome measures

Primary outcome

Whether ICG enhanced NIRF imaging is able to detect sentinel lymph nodes as good as or better than the standard technique (technetium-99 labelled colloid and Patent Blue) during breast surgery in 97%± 2% of the cases.

Secondary outcome

The number of lymph nodes detected by ICG enhanced NIRF imaging during breast surgery.

Study description

Background summary

In breast cancer patients undergoing breast-conserving surgery, tumour excision (lumpectomy) is often combined with a so-called sentinel lymph node procedure. Within the field of surgical oncology, the surgeon-oncologist lacks real-time intraoperative feedback on surgical margin status and locoregional metastasis. As a consequence, both over- and undertreatment common during breast-conserving surgery. Overtreatment is present when the surgeon excises an abundant amount of healthy breast tissue, which inevitably leads to dissapointing cosmetic results. Undertreatment, on the contrary, is defined as the presence of postive surgical margins after the excision of the primary tumour. Positive surgical margins necessitate re-excission or additional radiation to the breast and may result in increased psychological distress for the patient, physical comorbidity, logistical problems and cost/technical problems. Furthermore, the surgeon lacks trusthworthy information on the presence and location of affected locoregional lymph nodes. This could lead to e.g. unnessacery lymph node dissections in breast cancer patients. In up to 70% of all patients in who the

sentinel lymph node is affected, the backlaying lymph node bassin is free of metastasis. However, in the current standard of treatment, these unaffected lymph nodes are disected as well, which could lead to unnessacary mobidity including lymphoedema, disruption of sensibility or motor functions and an increased risk for infection of the affected arm.

In close collaboration with the Technical University of Munich, we developed a state-of-the-art camera system for intra-operative fluorescence imaging in vivo. Recently, this camara system, enhanced with the fluorescent dye 'indocyanin green' (ICG), was tested clinically in 10 stadium I-II breast cancer patients (METc 2008.298). By utilizing this system, we were able to detect subcutane lymph tracks and lymph nodes in real-time. As the feasibility study in these 10 patients has been succesful, we now will move on towards evaluating the value of near-infrared fluorescence (NIRF) optical imaging during the sentinel lymph node procedure in breast cancer patients.

Indocyanin green (ICG) has been extensively tested in human beings and is registered for several medical applications. The use of ICG enhanced NIRF optical imaging might improve the detection of the sentinel lymph node and related lymph nodes, which could decrease both the over- and undertreatment of breast cancer patients with a T1-2N0 status. Ultimately, this might result in decreased re-excision rates, psychological distress, co-morbidity and general health costs.

In the current non-inferiority study, the value of ICG enhanced NIRF optical imaging for the detection of the sentinel lymph node will be evaluated with respect to the current standard of treatment (radiocolloid + patent blue). It is expected that ICG enhanced NIRF optical imaging will be as least as or even more succesful in detecting the sentinel lymph node than the current standard.

Study objective

This study aims at evaluating whether indocyanin green (ICG) enhanced intra-operative near-infrared fluorescence (NIRF) imaging is as good as or even better than the standard technique (technetium-99 labeled colloid and Patent Blue) in detecting sentinel lymph nodes in breast-conserving surgery.

Study design

Interventional study: Treatment, Non-randomized, Open Label, Controlled, Single Group Assignment, Active-control Non-inferiority design.

Study burden and risks

Anaphylactic and allergic reactions have been reported in patients with or without a history of iodine allergy. The incidence of an anaphylactic reaction

is lower than 1/10.000 cases after intravenous administration. A green discoloration of the skin at the side of injection has been described. In all cases the discoloration disappeared within two weeks. No potential benefits, beside the feasibility of Indocyanine Green as a fluorescent contract agent, will be expected.

The burden associated with participation consists of an additional injection of indocyanin green (ICG) intratumoural besides patent blue during anaesthesia for the detection of the SLN. Additionally, there is a chance of elongation of the operative procedure by using a NIRF imaging device for up to 30 minutes.

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

Women above the age of 21 who have biopsy-proven breast cancer stage I-II, and who are undergoing sentinel lymph node mapping for staging and treatment of their disease.

Exclusion criteria

Pregnant women, hyperthyroidism, significant renal (serum creatinin >= 400 µmol/L), cardiac or pulmonary disease (ASA III-IV), history of iodine allergy or analfylactic reaction to insect bites or medication.

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2019
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ICG Pulsion ®
Generic name:	indocyanin green
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	06-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2009-011079-57-NL
CCMO	NL27380.042.09