Detection of breast carcinoma with an ICG enhanced optical imaging device in breast cancer patients.

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Ergonomics and function of the imaging system - the NIRF imaging system should not interfere with the standard lumpectomy procedure and used safely by the surgeon while detection of ICG within the tumour takes place. Duration: 1,5 hour clinical...

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-OMON33137

Source
ToetsingOnline

Brief title
ICG enhanced optical imaging in breast cancer.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, lumpectomy

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, ICG, Intra-operative, Optical imaging

Outcome measures

Primary outcome

Primary Objective:

* Ergonomics and function of the imaging system - the NIRF imaging system

should not interfere with the standard lumpectomy procedure and be used safely

by the surgeon while detection of ICG takes place. Duration: 1,5 hour clinical

procedure

Secondary outcome

none

Study description

Background summary

Breast cancer is the most common form of cancer and second leading cause of death in women in Europe and the USA, with 450,000 new cases and 120.000 deaths yearly. Over the last thirty years, wide-spread mammographic screening, technological developments and raised physicians- and self-awareness have led to a rapid increase in the diagnosis of small, non-palpable breast cancer. Surgery of primary breast cancer is dependent on the resection of the primary tumor and identification of cancer spread to lymph nodes (LNs), both independent prognostic factors for survival and recurrence of disease. Since breast sparing lumpectomy combined with radiotherapy is generally sufficient as a treatment for T1-T2 breast tumours in appropriately selected patients, breast conserving therapy (BCT) has become the standard treatment. BCT is considered to be less stressful compared to radical mastectomy and offers better cosmetic results and reduced wound infection risk. The most important disadvantage of BCT is the life-long risk for local recurrence of the primary tumour, in which case additional surgery is necessary. In 20-40% of the patients, after primary excisions there are positive resection margins. With new imaging technologies, this number may be reduced. In case of breast conserving treatment the aim of the procedures is to obtain optimal locoregional control with optimal cosmetic

results. New innovative imaging modalities like NIRF imaging intend to improve the detection of resection margins to be positive for tumor. This may decrease the number of re-excisions and/or irradiation, and ultimately leading to decreased costs, decreased co-morbidity and decreased psychological distress on the patient.

Study objective

Ergonomics and function of the imaging system - the NIRF imaging system should not interfere with the standard lumpectomy procedure and used safely by the surgeon while detection of ICG within the tumour takes place. Duration: 1,5 hour clinical procedure.

Study design

Interventional study: a phase 0 technical feasibility study / non-randomized, open label, uncontrolled, single group assignment.
The study will be carried out in collaboration with the Technical University of Munich, Institute of Biological and Medical Imaging. The actual study will be carried out at the University Medical Center Groningen, Department of Surgery.

The study protocol is designed as follows:
1. Selection of patients with operable histology proven invasive breast cancer (T1-2cN0-1) are asked for participation and informed consent at the outpatient clinic for the proposed study if the apply to the inclusion criteria. Copies of the proposed study protocol are available at the outpatient clinic. Patients have at least 24 hours to decide whether they want to participate or not.
2. After approval and documented informed consent, a pregnancy test is performed and in case of a positive test the patient cannot be included. Next, the operative procedure is planned together with the NIRF imaging protocol. The pharmacist of the UMCG is informed of inclusion of the patient together with the planned date of operation for delivery of ICG.
3. at the day of admission (one day prior to surgery), the standard surgical procedure for lumpectomy, combined with ICG intravenous injection in the operating room (OR) is again explained to the patient.
4. the day prior to surgery, the ICG compound will be delivered by the Hospital Pharmacy at the OR for i.v. injection.
5. during anesthesia ICG will be injected with a dose of 0.3 mg/kg (i.e. 1 ml of volume in a dose of 5 mg/ml).

Study burden and risks

The burden associated with participation consists of an additional injection of indocyanin green (ICG) i.v. during anaesthesia for the detection of the primary tumour. Additionally, there is a chance of longer operative procedure by using a NIRF imaging camera (~30 minutes).

1. The possible most serious adverse event for injection of ICG is an allergic and anaphylactic reaction.
2. The possible effect of prolonged anesthesia because of testing the camera system and detection of the primary tumour is limited in itself because of a total time of no longer than 2 hours.
3. There is no risk or burden of using the intraoperative imaging device, all necessary test for use of electrical devices in the OR are covered.
4. There is no risk of infection; the imaging device will be covered by special designed sterile drapes to prevent the risk of infection during a surgical procedure.

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 who are undergoing lumpectomy

Exclusion criteria

Pregnant women, significant renal, cardiac or pulmonary disease, history of iodine allergy or anaphylactic reactinos to insect bites or medication, presence or history of hyperthyroidism

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):	15-09-2009
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	15-06-2009
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	EUCTR2008-007156-10-NL
CCMO	NL27014.042.09