Evaluatie van een nieuwe optische beeldvormingstechniek voor de detectie van het mammacarcinoom bij patiënten met borstkanker.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22989

Source
NTR

Brief title
NIRF-guided tumour detection.

Health condition

Breast cancer.

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG), Department of Surgery.
Source(s) of monetary or material Support: University Medical Center Utrecht (UMCG), Department of Surgery.

Intervention

Outcome measures

Primary outcome

The primary outcome of this pilot study is the feasibility of intra-operative detection of breast carcinoma with an ICG enhanced optical imaging device.

Secondary outcome

N/A

Study description

Background summary

Rationale: ICG is a blood pool agent which is expected to delineate tumours by the fact that there are leaky vessels originating from angiogenesis from which the compound leaks into the tumour and surrounding tissue. After intravenous injection of ICG, tumour cells may be detected and visualized with a near-infrared fluorescence (NIRF) optical imaging system, thereby offering the surgeon real-time intra-operative information on tumour location and margin status without changing the surgical procedure itself. It is expected that optical imaging will enable the surgeon to detect (diagnostic) and at the same time excise (therapeutic) malignant tissue and any residual disease during breast-conserving surgery, thereby decreasing the number of re-excisions needed after BCT. This pilot study is designed to determine the feasibility of a novel optical imaging device enhanced with ICG for the intra-operative detection of breast carcinoma. Subsequently, this might provide a platform technique for patient tailored surgical interventions and tumour-specific contrast agents in the future.

Study objective

This pilot study hypothesizes that ICG enhanced near-infrared fluorescence (NIRF) optical imaging enables the intra-operative detection of breast carcinoma in breast cancer patients.

Study design

Day of surgery.

Intervention

At the start of the surgery and during anesthesia, the patient receives an intravenous injection with ICG compound in the cephalic vein. The lumpectomy procedure is followed in accordance with conventional guidelines. During the actual lumpectomy, the presence of ICG leakage in the tumour vasculature is assessed by holding a near-infrared fluorescence optical imaging device directly above (~20 cm) the region of interest (operative field).

Contacts

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Eligibility criteria

Inclusion criteria

Women above the age of 18 who have biopsy-proven stage I-II breast cancer and who are planning to undergo lumpectomy as a treatment for their disease.

Exclusion criteria

1. Refusal of the patient to be included in the study;

2. Pregnant or breast-feeding;

3. Significant renal dysfunction (serum creatinine above 400 micromol/L);

4. Significant cardiac and/or pulmonary disease (ASA III-IV);

5. History of iodine allergy or anaphylactic reactions to insect bites or medication;

6. Presence or history of hyperthyroidism;

7. Recent surgery on the breast.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-10-2009
Application type:	First submission

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
NTR-new	NL1965
NTR-old	NTR2082
Other	UMCG-NIRF : BICG02
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Sevick-Muraca EM, Sharma R, Rasmussen JC, Marshall MV, Wendt JA, Pham HQ, Bonefas E, Houston JP, Sampath L, Adams KE, Blachard DK, Fischer RE, Chiang SB, Elledge R, Mawad ME. Imaging of lymph flow in breast cancer patients after microdose administration of a near-infrared fluophore: Feasibility study. Radiology 2008; 246: 734-741.