Optical imaging for improved detection and surgery of solid tumors

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To test if an intraoperative NIRF camera system can detect a NIRF optical contrast agent for SLN in patients with palpable breast cancer.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21271

Bron
NTR

Verkorte titel
NIRF imaging

Aandoening

breast cancer, sentinel lymph node, intraoperative imaging, image-guided surgery

Ondersteuning

Primaire sponsor: Department of Surgery, University Medical Center Groningen
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Ergonomics and function of the NIRF imaging system - the NIRF imaging system must not interfere with the standard Sentinel Lymph Node mapping procedure and should be used safely by the surgeon.
Duration of data aquisition: 1,5 hour clinical procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

This project consists on the realization followed by the clinical validation of a medical instrument dedicated to sentinel lymph nodes identification and localization in the case of breast cancer. An intra operative near-infrared fluorescence imaging camera will be evaluated for its technical feasibility to detect the sentinel lymph node (SLN) in patients with breast cancer. The sentinel lymph node technique, based on the propagation of cancer cells in the lymphatic system, allows a better evaluation of tumor staging, prognosis and therapeutic strategy determination. The end-goal of this intraoperative imaging instrument, designed by physicians and physicists, is to significantly improve the detection and efficiency of the technique in order to reduce the false negative rate and then the recurrence risk, as well as the operative morbidity. Clinical oncologist surgeons and fundamental physics applied to medical imaging researchers are involved in this project.

Objective:
To test if an intraoperative NIRF camera system can detect a NIRF optical contrast agent for SLN in patients with palpable breast cancer.

Doel van het onderzoek

To test if an intraoperative NIRF camera system can detect a NIRF optical contrast agent for SLN in patients with palpable breast cancer.

Onderzoeksopzet

Day of surgery

Onderzoeksproduct en/of interventie

Patients with palpable operable invasive breast cancer stage I-II undergoing a lumpectomy, combined with a sentinel lymph node procedure, will receive prior to a lumpectomy and SLN procedure an intratumoral injection with indocyanin green (ICG).

During the operative procedure NIRF imaging for detection of the SLN (i.e. ICG accumulation) will take place.

Contactpersonen

Publiek

University Medical Center Groningen
Department of Surgery / BioOptical Imaging Center Groningen

G.M. Dam, van
Hanzeplein 1

Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Wetenschappelijk

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Department of Surgery / BioOptical Imaging Center Groningen

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The Netherlands
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with operable invasive breast cancer stage (T1-2N0-1 – stage I and II) proven by histology on a biopsy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnant women.

2. Significant renal (creatinine >, cardiac, or pulmonary disease (ASA III-IV).

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

4. Presence or history of hyperthyroidism.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-10-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1430
NTR-old	NTR1492
Ander register	: BICG01UMCG-NIRF
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
- Intraoperative identification of sentinel lymph nodes by near-infrared fluorescence imaging in patients with breast cancer. Tagaya N, Yamazaki R, Nakagawa A, Abe A, Kiyoshige H, Kubota K, Oyama T. Am J Surg 2008;195:850-853.

- Evaluation of breast lymphatic pathways with indocyanine green fluorescence imaging in patients with breast cancer. Ogasawara Y, Ikeda H, Takahashi M, Karasaki K, Doihara H. World J Surg 2008;32:1924-1929.

- Imaging of lymph flow in breast cancer patients after microdose administration of a near-infrared fluophore: Feasibility study. 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. Radiology 2008; 246: 734-741.

