

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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27252

Source

NTR

Brief title

NIRF SLNB

Health condition

breast cancer, sentinel lymph node procedure, image-guided surgery, schildwacht klier procedure, borstkanker

Sponsors and support

Primary sponsor: University Medical Center Groningen, Department of Surgery

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

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 $97\% \pm 2\%$ of the cases.

Secondary outcome

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

Study description

Background summary

Rationale:

This project consists on the clinical validation of an imaging modality 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 ability to detect the sentinel lymph node (SLN) in patients with breast cancer compared to the standard procedure in a non-inferiority study design. 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 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 in future studies on near-infrared tumor-targeted optical contrast agents.

Study objective

This non-inferiority study specifies as a null hypothesis that ICG enhanced NIRF imaging is inferior in detecting sentinel lymph nodes compared to the current standard treatment (technetium-99m combined with Patent Blue).

Study design

Day of surgery.

Intervention

Patients with operable 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.

Contacts

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Eligibility criteria

Inclusion criteria

Patient with operable stage I-II breast cancer diagnosed preoperatively by core biopsy or cytology (cT1-2N0).

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. 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 armpit.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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	NL1616
NTR-old	NTR1700
Other	ICG enhanced SLNB : BICG26UMCG-NIRF
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

1. 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.

2. 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.

3. Imaging of lymph flow in breast cancer patients after microdose administration of a near-infrared fluophore: Feasibility study. Sevic-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.