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

Gepubliceerd: 09-03-2009 Laatst bijgewerkt: 18-08-2022

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).

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27252

Bron
NTR

Verkorte titel
NIRF SLNB

Aandoening

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

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

Day of surgery.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

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 nog niet gestart
(Verwachte) startdatum:	01-05-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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

Resultaten

Samenvatting resultaten

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. 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.