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

Gepubliceerd: 28-10-2009 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22989

Bron
NTR

Verkorte titel
NIRF-guided tumour detection.

Aandoening

Breast cancer.

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG), Department of Surgery.
Overige ondersteuning: University Medical Center Utrecht (UMCG), Department of Surgery.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Day of surgery.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

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. 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	10-01-2009
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2009
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	NL1965
NTR-old	NTR2082
Ander register	UMCG-NIRF : BICG02
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
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.