Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij borstkankerpatienten.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23204

Source
NTR

Brief title
GREEN LIGHT

Health condition

Breast cancer
Borstkanker

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Fund=initatior=sponsor
Additional funding from:
CTMM
American Women's Club
ZonMw
Maurits en Anne de Kock Stichting

Intervention

Outcome measures

Primary outcome

Identification rate, defined as the proportion of patients in whom sentinel and non-sentinel lymph nodes was identified percutaneously with the fluorescent signal of ICG:HSA

Secondary outcome

1. Median number of lymph nodes identified with ICG:HSA and standard SNB;

2. Identification rate of standard SNB;

3. Sensitivity: percentage of patients in whom fluorescent lymph nodes were identified of the total patients with identified sentinel lymph nodes by standard SNB technique;

4. Improvement in false-negative rate.

Study description

Background summary

Although sentinel lymph node procedure (SLNP) is regarded standard of care, the technique is not optimal and it requires involvement of ionizing radiation. Fluorescent imaging using near-infrared probes is an innovative technique to directly visualize lymphatic pathways and lymph nodes. Our experimental camera system has been validated in large animal models.

A phase I single-institution feasibility trial followed by a phase II non-randomized, open-label, single-institution diagnostic efficacy trial if proven feasible in detecting axillary lymph nodes in humans during phase I.

Study objective

Fluorescent near-infrared imaging can accurately detect lymph nodes percutaneously and non-invasively during SLNP in breast cancer patients.

Study design

The primary and secondary outcomes will be assessed during surgery and pathological assessment.

Intervention

Standard SLNP will be performed. Before axillary incision, the near-infrared dye ICG:HSA will be injected and lymphatic pathways and lymph nodes will be visualized non-invasively and percutaneously using our experimental camerasystem.

Contacts

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Eligibility criteria

Inclusion criteria

Breast cancer patients planned to undergo a sentinel lymph node procedure.

Exclusion criteria

1. History of allergy to iodine, shellfish, indocyanine green or human serum albumin;

2. Pregnancy;

3. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2009
Enrollment:	53
Type:	Actual

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	NL1967
NTR-old	NTR2084
Other	METC LUMC : CME Leiden P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A