Gerandomiseerde vergelijking tussen het gebruik van indocyanine groen, patent blauw en radioactiviteit en het gebruik van indocyanine groen en radioactiviteit bij 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-OMON29519

Source
Nationaal Trial Register

Brief title
GREEN LIGHT

Health condition

breast cancer

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC), KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

Signal-to-background ratio of identified SLNs, defined as the fluorescence intensity of SLN divided by the fluorescence intensity of the surrounding background.

Secondary outcome

1. Number of identified SLNs: fluorescence and non-fluorescence;

2. In vivo and ex vivo fluorescence intensity of SLNs;

3. Identification ratio;

4. Percutaneous lymphatic channel identification;

5. Time to identification of SLN.

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.

In this study, randomisation will be performed between using patent blue and omitting patent blue. In all patients, ICG and radiocolloid will be used.

Study objective

ICG alone combined with radioactivity will perform better than ICG combined with patent blue and radioactivity.

Study design

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

Intervention

A Randomized Single-Institution Superiority Trial comparing standard of care SLN (radioactive tracer and blue dye) + ICG fluorescence and SLN mapping using only radiocolloid (omitting patent blue) + ICG fluorescence in breast cancer patients undergoing SLN procedure.

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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:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2011
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	03-01-2011
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	NL2556
NTR-old	NTR2674
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A