Gerandomiseerde vergelijking tussen indocyanine groen en indocyanine groen gekoppeld aan humaan serum albumine bij intra-operatieve fluorescente beeldvorming van schildwachtklieren bij vulva kanker patienten.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26660

Source
NTR

Brief title
GREEN LIGHT

Health condition

vulvar cancer

Sponsors and support

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

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 ICG:HSA and ICG alone.

Study objective

ICG alone without being absorbed to albumin can be used for near-infrared fluorescence SLNB in vulvar cancer patients.

Study design

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

Intervention

Standard SLNP will be performed. Before incision, the near-infrared dye ICG:HSA of ICG alone

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

Vulvar 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:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2011
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-04-2011
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	NL2733
NTR-old	NTR2871
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A