Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij vulva kanker.

No registrations found.

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

Summary

ID

NL-OMON23796

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: ZON-MW, The Netherlands Organization for Health Research and Development, Leiden University Medical Center (LUMC), Center for Translational Molecular Medicine (CTMM), American Women's Club, Maurits Anne de Kock Stichting, KWF kankerbestrijding

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.

Study objective

Fluorescent near-infrared imaging can accurately detect lymph nodes percutaneously and non-invasively during SLNP 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 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:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2010
Enrollment:	12
Type:	Actual

Ethics review

Positive opinion

Date:	25-08-2010
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	NL2372
NTR-old	NTR2479
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A