Intraoperatieve detectie van de schildwachtklier met indocyanine groen gecombineerd met radioactief Nanocoll bij vulva kanker patienten.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20197

Source
Nationaal Trial Register

Brief title
GREEN LIGHT

Health condition

Vulvar cancer

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. The proportion of patients in whon sentinel and non-sentinel lymph nodes can be

identified;

2. Difference in signal-to-background ratio between different injection groups.

Secondary outcome

1. Carrelation between fluorescent and radioactove nodes;

2. The correlation between the quantitative fluorescence signal and quantitative radioactive signal.

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. In previous experiment we succesfully identifies SLNs with fluorescent imaging. In this study, a combined fluorescent and radioactive probe is used for SLN identification.

Study objective

ICG combined with 99Tc-Nanocoll can be used as fluorescent tracer in sentinel lymph node mapping 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. One day before surgery or the day of surgery. 99TC-Nanocoll-ICG will be injected and lymphatic pathways and lymph nodes will be visualized non-invasively and percutaneously using our experimental camerasystem during surgery.

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:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2013
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	NL3679
NTR-old	NTR3849
Other	METC Leiden : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A