Nabij-infrarode fluorescente beeldvorming gecombineerd met radioactieve colloiden voor de schildwachtklierprocedure in patienten met huidkanker.

No registrations found.

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

Summary

ID

NL-OMON24324

Source
Nationaal Trial Register

Brief title
GREEN LIGHT

Health condition

Melanoma

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

NIR fluorescence identification ratio of the SLN, defined as the proportion of patients in whom sentinel and non-sentinel lymph nodes were identified using NIR fluorescence.

Secondary outcome

1. Signal to background ratio of the SLNs;

2. Number of identified SLNs: fluorescence a nd non-fluorescence;

3. In vivo and ex vivo fluorescence intensity of SLNs and radioactivity of the SLNs;

4. Percutaneous lymphatic channel identification at multiple time points;

5. Time to identification of SLN.

Study description

Background summary

Combining radioactive colloids and a near-infrared fluorophore permits both preoperative planning and intraoperative localization of deeply located sentinel lymph nodes (SLNs) with direct optical guidance using a single lymphatic tracer. This study aims to evaluate and optimize a hybrid NIR fluorescence and radioactive tracer for SLN detection in melanoma patients.

Study objective

A tracer coctail combining indocyanine green and radioactive colloids will allow enhanced detection of the sentinel lymph node in melonoma patients.

Study design

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

Intervention

A feasibility single-institution trial to assess the use of ICG combined with 99mTc-nanocolloid as a cocktail in SLN mapping in melanoma patients. Standard-of-care SLN mapping will be performed (blue dye staining and radiocolloid).

Contacts

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Eligibility criteria

Inclusion criteria

Melanoma 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:	Recruiting
Start date (anticipated):	01-11-2011
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	NL3680

Register	ID
NTR-old	NTR3850
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A