Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij blaaskankerpatienten.

No registrations found.

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

Summary

ID

NL-OMON26333

Source
NTR

Brief title
GREEN LIGHT

Health condition

Bladder cancer

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

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;

2. Sensitivity: percentage of patients in whom fluorescent lymph nodes were identified of the total patients with identified sentinel lymph nodes by standard SNB technique;

3. signal-to-background ratio.

Study description

Background summary

A new and still experimental lymphadenectomy approach in bladder cancer is to identify, remove, and analyze a sentinel lymph node (SLN) or nodes. Fluorescent imaging using near-infrared probes is an innovative technique to directly visualize lymphatic pathways and lymph nodes. We hypothesize that an ICG coupled to human serum albumin would provide a highly sensitive, high-resolution image of SLNs.

Study objective

Fluorescent near-infrared imaging can accurately detect lymph nodes non-invasively during SLN mapping in bladder cancer patients.

Study design

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

Intervention

Standard lymphadectomy will be performed. Before surgery, the near-infrared dye ICG:HSA will be injected and lymphatic pathways and lymph nodes will be visualized non-invasively using our experimental camerasystem.

Contacts

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Eligibility criteria

Inclusion criteria

Bladder cancer patients planned to undergo a wide local excision and lymphadenectomy.

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):	01-05-2010
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-10-2012
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	NL3477
NTR-old	NTR3657
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A