Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij baarmoederhalskankerpatienten.

No registrations found.

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

Summary

ID

NL-OMON22239

Source
NTR

Brief title
GREEN LIGHT

Health condition

Cervical 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 en 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 with the fluorescent signal of ICG:HSA.

Secondary outcome

Median number of lymph nodes identified with ICG:HSA.

Study description

Background summary

Although sentinel lymph node procedure (SLNP) is not regarded standard of care, the technique can potentially be implemented in cervical cancer patients. 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 sentinel lymph nodes non-invasively during lymphadenectomy in cervical cancer patients.

Study design

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

Intervention

Standard lymphadenectomy will be performed. Before median laparotomy, the near-infrared dye ICG:HSA will be injected peritumorally around the cervix and lymphatic pathways and lymph nodes will be visualized non-invasively using our experimental camerasystem.

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Surgical Oncology,
P.O. Box 9600
C.J.H. Velde, van de
Leiden 2300 RC

The Netherlands
+31 (0)71 5262309
Scientific
Leiden University Medical Center (LUMC),
Department of Surgical Oncology,
P.O. Box 9600
C.J.H. Velde, van de
Leiden 2300 RC
The Netherlands
+31 (0)71 5262309

Eligibility criteria

Inclusion criteria

Cervical cancer patients planned to undergo a 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:	Recruitment stopped
Start date (anticipated):	01-08-2010
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	NL2373
NTR-old	NTR2480
Other	METC LUMC : P09.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A