Evaluation of near-infrared fluorescence (NIRF) imaging for detection of lymph nodes (LN) in cervical cancer: a feasibility study

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to determine the feasibility of real-time detection and quantification of two NIRF optical contrast agents in the detection of sentinel and metastatic LNs in patients with cervical cancer during surgery with a novel NIRF imaging device to provide a...

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON33291

Source
ToetsingOnline

Brief title
LN detection in cervical cancer

Condition

- Reproductive neoplasms male malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym
cervical cancer, sentinel node procedure

Research involving
Human

Sponsors and support

Primary sponsor: Gynaecologie & Obstetrie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cervical cancer, Folate-FITC, Indocyanin Green, Sentinel lymph node

Outcome measures

Primary outcome

To assess the detection and location of metastatic (sentinel) lymph nodes in

patients with primary cervical cancer, by using a NIRF camera system.

Secondary outcome

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Study description

Background summary

In surgical and gynaecological oncology, it can be difficult for the surgeon or gynaecologist to determine tumour margins and lymph node (micro)metastases intra-operatively. In order to remove all possible metastases, a complete bilateral pelvic lymphadenectomy is performed in the case of cervical cancer. Most of the time, not all lymph nodes are affected, leading to overtreatment and more co-morbidity than in the case of a more selective excision of lymph nodes.

In collaboration with the technical University of Munich, we have acquired an intra-operative imaging system for fluorescence imaging. This could help the gynaecologist in detecting tumour margins by providing real-time information on tumour margins and lymph node metastases. In this research application, the system will be tested with two fluorescent probes (one for lymph node metastases, one for the sentinel node) in ten patients with cervical cancer. The main outcome criterium is the possibility to detect the fluorescent signal in lymph nodes, which will be examined histopathologically ex vivo.

Study objective

to determine the feasibility of real-time detection and quantification of two NIRF optical contrast agents in the detection of sentinel and metastatic LNs in patients with cervical cancer during surgery with a novel NIRF imaging device to provide a platform technique for patient-tailored surgical interventions in the future.

Study design

interventional phase 0 technical feasibility study / non-randomized, open label, uncontrolled, single group assignment.

Study burden and risks

Patients with cervical cancer undergoing surgery (radical hysterectomy with bilateral pelvic lymphadenectomy), will receive an intravenous injection with folate-FITC four hours prior to surgery, followed by a peritumoural injection with Indocyanine Green (ICG) and patent blue after administration of full anaesthesia. During the operative procedure NIRF imaging for detection of the SLN or metastatic LNs (i.e. ICG and patent blue and/or folate-FITC accumulation) will take place.
The only risk is an anaphylactic reaction against ICG or folate-FITC. This has seldomly been described. Therefore, patients will be monitored for 24 hours after injection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

women > 21 years of age with biopsy proven cervical cancer who are scheduled to undergo hysterectomy with pelvic lymphadenectomy

Exclusion criteria

Pregnant women, renal failure, cardiac or pulmonary diseases, allergy against iodine, previous anaphylactic or allergic reactions against insect bites or medication, hyperthyreoidism

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2009
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Product type:	Medicine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-05-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2009-010560-42-NL
CCMO	NL26981.042.09