Evaluation of a Clinical Prototype Near-InfraRed Fluorescence (NIRF) Imaging Device for Lymph Node Mapping in Esophageal Cancer: a Technical Feasibility Study

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Primary: Evaluate the ergonomics and function of the imaging system - the NIRF imaging system should not interfere with the standard esophagus resection and lymphadenectomy procedure by the surgeon while detection of indocyanine green (ICG) takes...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON33445

Source
ToetsingOnline

Brief title
Lymph Node Mapping with NIRF in Esophageal Cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym
Esophageal cancer, Gullet cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Esophageal Cancer, Indocyanin Green, Lymph Node Mapping, NIRF

Outcome measures

Primary outcome

Ergonomics and function of the NIRF imaging system - the NIRF imaging system must not interfere with the standard esophagectomy and lymphadenectomy procedure and should be used safely by the surgeon. Duration of data acquisition: ~30 minutes.

Secondary outcome

Identify draining lymph nodes within the allocated procedure (usually 4-6 hours)

Study description

Background summary

Esophageal cancer is the 6th leading cause of cancer-related death in the world, and its incidence is increasing dramatically in the western world. The mainstay of curative treatment is esophagectomy. Current limitations in surgery are inadequate lymphadenectomy (too few or no lymph nodes), inadequate primary tumor resection (involved resection margins, circumferential resection margin <= 1 mm, microscopic or macroscopic irradical resection) and undetected distant metastases, all of which result in a poorer outcome for the patient. The detection of lymph nodes, based on the propagation of cancer cells in the lymphatic system, allows a better evaluation of tumor staging, prognosis and therapeutic strategy determination.

This project intends to investigate a new medical instrument for mapping draining lymph nodes and provide real-time feedback for the surgeon. An intra-operative Near Infrared Fluorescence (NIRF) camera will be evaluated for its technical feasibility to detect draining lymph nodes from esophageal cancer. In course, this technique will be expanded upon by introducing folate receptor fluorescein-isothiocyanate (FITC). The end-goal of this intraoperative imaging instrument, designed by physicians and physicists, and its combination with a folate-FITC optical contrast agent is to improve the detection of involved lymph nodes, tumor delineation and distant metastases at the pleura or peritoneum. By doing so, it may increase the efficiency and completeness of resection, ultimately resulting in a better outcome for the patient. Clinical oncologist surgeons and fundamental physics applied to medical imaging researchers are involved in this project.

Study objective

Primary:
Evaluate the ergonomics and function of the imaging system - the NIRF imaging system should not interfere with the standard esophagus resection and lymphadenectomy procedure by the surgeon while detection of indocyanine green (ICG) takes place for lymph node mapping. Duration: ~30 minutes real-time .

Secondary:
To test if an intraoperative NIRF camera system can detect a NIRF optical contrast agent for lymph nodes, and their numbers, in patients with operable esophageal cancer.

Study design

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

Intervention

Patients with operable esophageal cancer undergoing esophagectomy with two-field-lymphadenectomy, either by a left- or right-sided abdomino-thoracotomy, will receive pre-operatively an intratumoral injection with indocyanine green (ICG) during endoscopy guided by ultrasound (EUS). During the operative procedure NIRF imaging for detection of draining lymph nodes (i.e. ICG accumulation) will take place.

Study burden and risks

The burden associated with participation consists of an injection of indocyanine green (ICG) intratumoral intra-operatively for the detection of the draining lymph nodes. Additionally, there is a chance of longer operative

procedure by using a NIRF imaging camera (~30 minutes).
1. The possible most serious adverse event for injection of ICG is an allergic and anaphylactic reaction, as described in the SPC.
2. The possible effect of prolonged anesthesia because of testing the camera system and detection of the lymph nodes is limited in itself because lymph node mapping is executed during the actual surgery. Nevertheless, we will limit imaging time, and possible prolongation of the procedure to a maximum of 60 minutes.
3. There is no risk or burden of using the intraoperative imaging device, all necessary test for use of electrical devices in the OR are covered.
4. There is no risk of infection; the imaging device will be covered by special designed sterile drapes to prevent the risk of infection during a surgical procedure.

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

Resectable esophageal carcinoma
> 21 years

Exclusion criteria

Significant renal, cardiac, or pulmonary disease (ASA III-IV)
History of iodine allergy or anaphylactic reactions to insect bites or medication Presence or history of hyperthyroidism

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ICG-Pulsion ® 25 mg
Generic name:	Indocyanine Green: 2-{7-[1.1-dimethyl-3-(4-sulfobutyl)-benz[e]indolin-2-ylidene]-1,3,5-heptatrienyl}
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	09-07-2009
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	EUCTR2009-011083-11-NL
CCMO	NL27638.042.09