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

No registrations found.

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

Summary

ID

NL-OMON27000

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Esophageal cancer

Sponsors and support

Primary sponsor: University Medical Centre Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands
Source(s) of monetary or material Support: University Medical Centre Groningen
Hanzeplein 1
9700 RB Groningen
The Netherlands

Intervention

Outcome measures

Primary outcome

Application of the near-infrared fluorescence camera safely without disturbing the normal operative procedure.

Secondary outcome

Detection of lymph nodes with the near-infrared fluorescence camera.

Study description

Background summary

The primary aim of the study is to assess whether our Near-Infrared Fluorescence camera may safely be used during esophageal resections. The secondary aim is the intraoperative detection of lymph nodes using indocyanine green and a Near-Infrared Fluorescence camera.
Patients undergoing esophagectomy for cancer of the esophagus will receive an intraoperative peritumoral injection with ICG. Imaging will subsequently take place using the NIRF camera to assess whether lymph nodes may be detected.

Study objective

A near-infrared fluorescence camera and a peritumoral injection of indocyanine green may be used for detection of lymph nodes during esophageal resections without affecting the normal operative procedure.

Study design

N/A

Intervention

Peritumoral injection with indocyanine green and subsequent imaging using the intraoperative near-infrared fluorescence camera.

Contacts

Public
University Medical Center Groningen
Department of Surgery / BioOptical Imaging Center Groningen

G.M. Dam, van
Hanzeplein 1

Groningen 9700 RB
The Netherlands
+31 (0)50 3612283
Scientific
University Medical Center Groningen
Department of Surgery / BioOptical Imaging Center Groningen

G.M. Dam, van
Hanzeplein 1

Groningen 9700 RB
The Netherlands
+31 (0)50 3612283

Eligibility criteria

Inclusion criteria

Men and women above the age of 21 who have biopsy-proven esophageal cancer that is deemed operable by the treating surgeon by the current staging protocol at the UMCG (i.e. endoscopy, endo ultrasound, CT thorax/abdomen, PET scan).

Exclusion criteria

1. Significant renal, cardiac, or pulmonary disease (ASA III-IV);

2. History of iodine allergy or anaphylactic reactions to insect bites or medication;

3. Presence or history of hyperthyroidism.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-06-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-09-2009
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	NL1889
NTR-old	NTR2003
Other	UMCG : BICG08UMCG-NIRF
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A