Evaluation of gastric conduit perfusion with near infrared fluorescence imaging during esophagectomy: a pilot study

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This study is designed to assess the feasibility of NIRF with ICG during open or minimal invasive esophagectomy in order to assess the gastric conduit perfusion.

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

Summary

ID

NL-OMON46607

Source
ToetsingOnline

Brief title
EGAPERF (Evaluation of GAstric conduit PERFusion

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
esophageal 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: Anastomotic leakage, Esophageal neoplasms, Esophageal Surgery, Near infrared fluorescence

Outcome measures

Primary outcome

- Visualization of the perfusion of the gastric conduit and wash-in and

wash-out time of the ICG just before reconstruction of the anastomosis.

- Visualization of the perfusion of the anastomotic site after reconstruction

of the anastomosis, also measuring the wash-in and wash-out time of the ICG.

- Postoperative anastomotic leakage. Anastomotic leakage is defined as clinical

suspicion and confirmation by CT-scan of contrast, methylene blue, saliva or

other ingested material into the drain or signs of anastomotic leakage during

re-intervention or autopsy.

Secondary outcome

- Monitor the procedure time; the total time of the chirurgical procedure is

measured.

- Complications due to NIRF imaging with ICG

Study description

Background summary

Anastomotic leakage is a severe complication after esophagectomy and causes major complications and mortality. Local ischemia to the most distal part of the gastric conduit is thought to be the most important cause of anastomotic leakage. Better assessment of the perfusion of the gastric conduit and to identify the best level of the site of the anastomosis is needed. Near-infrared fluorescence (NIRF) of the gastric conduit with Indocyanine green (ICG) is a new technique to assess the gastric conduit perfusion. This technique is

already being used in some hospitals in the Netherlands and also wordwide.

Study objective

This study is designed to assess the feasibility of NIRF with ICG during open or minimal invasive esophagectomy in order to assess the gastric conduit perfusion.

Study design

Single center exploratory study

Study burden and risks

The included patient will undergo a esophagectomy with gastric conduit reconstruction for esophageal cancer. In addition to this major procedure patients will undergo NIRF imaging after intravenous ICG administration. No additional treatments, testing, clinical visits or assessments are required besides the standard patient care. Patients already have intravenous access during the operation. ICG can cause (mild) side-effects in less than 0.0001% of the patients.
Esophagectomy is a major procedure with a high morbidity and mortality. Anastomotic leakage is a known severe complications. As this is an exploratory study no clinical decision will be made on findings by fluorescence. It is expected that the number of complications will not be different from regular esophagectomy without ICG fluorescence. The outcome of this exploratory study will potentially be of great importance to determine the added value of intra-operative ICG fluorescence imaging to assess the gastric conduit perfusion.

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

- Patients scheduled for a minimal invasive (or open) esophagectomy for esophageal cancer with a gastric conduit reconstruction
- Aged 18 years or older
- Signed informed consent.

Exclusion criteria

- Known pregnancy or breastfeeding
- Known iodine, shellfish or ICG hypersensitivity
- Known hyper-thyroidism
- Known liver or renal insufficiency
- Unable to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2018
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	08-03-2018
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
CCMO	NL64038.042.17