Gastric conduit perfusion assessment by indocyanine green fluorescent imaging in minimally invasive esophagectomy; an exploratory study

Published: 12-10-2016
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This study is designed to explore the feasibility and added value of NIRF in minimally invasive esophagectomy and secondly to assess gastric conduit perfusion with intravenous injection of ICG.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON45919

Source
ToetsingOnline

Brief title
GAP-study

Condition

- Gastrointestinal therapeutic procedures

Synonym
esophageal cancer , esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anastomotic perfusion, Esophageal carcinoma, Esophagectomy, Fluorescence, ICG

Outcome measures

Primary outcome

To explore the feasibility and added value of NIRF to assess gastric conduit

perfusion in minimally invasive esophagectomy.

Secondary outcome

- Indentify the increase in procedure time

Study description

Background summary

Anastomotic leakage after esophagectomy is an early post-operative complication and a major cause of morbidity and mortality. Impaired arterial bloodflow of the gastric conduit is thought to be the most important cause of anastomotic leakage. Better assessment of gastric conduit perfusion and identification of the ideal level of anastomosis is needed. A promising technique to assess the gastric conduit perfusion intra-operatively is near-infrared fluorescence (NIRF) imaging after injection with indocyanine green (ICG).

Study objective

This study is designed to explore the feasibility and added value of NIRF in minimally invasive esophagectomy and secondly to assess gastric conduit perfusion with intravenous injection of ICG.

Study design

Single center exploratory study

Study burden and risks

Included patients are already considered for esophagectomy and will undergo an intravenous injection of ICG. This is the only additional (minimally) invasive

action for the patient. No additional treatments, testing, clinic visits or assessments are required besides the standard patient care. ICG can cause (mild) side-effects in less than 0.0001% of the patients. Esophagectomy is associated with high morbidity and mortality, in which anastomotic leakage plays an important role. However, since no clinical decisions will be made on findings by ICG fluorescence, the number of serious adverse events due to the surgical procedure is not expected to be different from regular esophagectomy without ICG fluorescence imaging. The outcome of this exploratory study will potentially be of great importance to determine the added value of intra-operative ICG fluorescence imaging for assessment of 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
* All patients eligible for minimally invasive esophagectomy for easophageal cancer, with gastric conduit reconstruction and intrathoracic gastro-esophageal anastomosis
* Aged 18 years or older
* Providing informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in the study:
* Known Liver or renal insufficiency
* Known pregnancy or breastfeeding
* Known iodine, shellfish or ICG hypersensitivity
* Unable to provide informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	27-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23045
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58179.091.16
OMON	NL-OMON23045

Study results

Date completed:	01-07-2019
Actual enrolment:	9