Fluorescent angiography using indocyanine green during esophagectomy with continuity restoration to prevent anastomotic complications

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24815

Source
Nationaal Trial Register

Brief title
FA UpperGI

Health condition

Esophageal cancer

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary outcomes are various quantitative parameters of FA, and to relate those parameters to surgical morbidity. Quantitative parameters include time to fluorescence in target or surrounding tissue.

Secondary outcome

Secondary outcomes include surgical morbidity, other FA details, and hemodynamic parameters. Surgical outcomes include anastomotic leakage, graft necrosis and anastomotic strictures. FA details include change in management and additional surgical time.

Study description

Background summary

Anastomotic complicaties after esophagectomy with continuity restoration are associated with a high mortality. Among the risk factors that influence anastomotic integrity, poor perfusion is a surgically modifiable factor. Intraoperative real-time fluorescence angiography (FA) using indocyanine green (ICG) can assess perfusion, and thereby enables precise delineation of the ideal site for anastomosis and assessment of final anastomotic vitality. Although management according to FA findings seems to lower anastomotic complications rates afer esophagectomy, complications still occur. Besides the multifactorial etiology of anastomotic complications, an explanation might be that no fluorescent threshold is known for complications.
In this monocenter prospective explorative study (IDEAL phase 2S study), we aim to evaluate time to fluorescent enhancement as a quantitative fluorescent value, and to correlate the values with surgical morbidity, including anastomotic leakage, graft necrosis and anastomotic strictures.

Study objective

Intraoperative real-time FA using ICG can assess perfusion, and thereby enables precise delineation of the ideal site for anastomosis and assessment of final anastomotic vitality. However, no quantitative threshold of the fluorescence signal is known for adequate perfusion. Time dependent change of the fluorescent signal seems a promising method for objective analysis of tissue perfusion. The hypothesis is that a quantitative threshold for this time dependent change can be identified to predict surgical morbidity.

Study design

Surgery and follow-up

Intervention

Intraoperative FA is performed after intravenous ICG injection (0.05mg/kg/bolus). Time to first fluorescent enhancement is assessed using a digital clock and will be noted in a case-report form.

Contacts

Public
Amsterdam UMC, location AMC
Maxime Slooter

0031 (0)20 566 2771
Scientific
Amsterdam UMC, location AMC
Maxime Slooter

0031 (0)20 566 2771

Eligibility criteria

Inclusion criteria

- Age of 18 years and older;
- Undergoing esophagectomy with gastric conduit reconstruction;
- Undergoing esophagectomy with continuity restoration, graft other than gastric conduit;
- Intraoperative FA to assess perfusion of graft and anastomosis;
- No objection for use of data.

Exclusion criteria

- Allergy to ICG, iodide or sodium iodide;
- Hyperthyroidism or benign thyroid tumor;
- Thyroid examination using radioactive iodide <1 week;
- Breast-feeding;
- Objection for use of data.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2018
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	14-04-2020
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	NL8527
Other	METC AMC : W19_145 (outside the realm of the Dutch WMO law)

Study results