Quantitative fluorescence-guided perfusion assessment of the anastomosis during gastrointestinal surgery

No registrations found.

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

Summary

ID

NL-OMON26683

Source
NTR

Brief title
Quant FA

Health condition

Patients that undergo FA-guided (1) esophagectomy (2) ileal pouch-anal anastomosis (IPAA), or (3) a partial or total mesorectal excision for colorectal cancer with restoration of bowel continuity will be included

Sponsors and support

Primary sponsor: prof. dr. M.I. van Berge Henegouwen, prof dr. P.J. Tanis, dr. R.Hompes
Source(s) of monetary or material Support: Stryker

Intervention

Outcome measures

Primary outcome

The main objective of this study is to evaluate quantitative FA-parameters before and after

anastomotic reconstruction, during (1) esophagectomy (2) IPAA and (3) a partial or total mesorectal excision with restoration of bowel continuity and to relate these parameters to patient outcomes, including anastomotic leakage.

Secondary outcome

The main secondary objective is to evaluate the relation between quantitative FA-parameters to hemodynamic parameters, including vitals and inotropic or vasopressive drug use.
Other secondary objectives include measuring differences in quantitative FA-parameters with different distances to the anastomosis, and the comparison of quantitative FA-parameters between arterial and venous ischemia.
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Study description

Background summary

Fluorescence angiography (FA) using indocyanine green (ICG) is a helpful intraoperative technique to assess perfusion of the anastomosis during gastrointestinal surgery. Management according to FA seems to lower anastomotic leakage rates. However, no threshold is known for adequate perfusion. To evaluate ICG fluorescence objectively, we aim to quantify the fluorescent signal of FA.
The main objective of this study is to evaluate quantitative FA-parameters before and after anastomotic reconstruction and relate the parameters to patient outcomes in terms of anastomotic leakage.

Study objective

The hypothesis is that the slope of the curve will predict patient outcomes

Study design

One year

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible for inclusion in this study, a patient must meet all of the following criteria:
- Age of 18 years and older;
- Informed consent
- Scheduled for one of the following options:
1. an esophagectomy for esophageal cancer with gastric conduit reconstruction;
2. proctocolectomy or completion proctectomy with IPAA for inflammatory bowel disease (IBD) or inherited colorectal cancer disorders;
3. a partial or total mesorectal excision for colorectal cancer with restoration of bowel continuity;

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded:
- Allergy to ICG, iodide or sodium iodide;
- Hyperthyroidism or benign thyroid tumour;
- Thyroid examination using radioactive iodide <1 week;
- Breast-feeding or pregnancy;
- No informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	199
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-05-2020
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	NL8653
Other	METC AMC : W20_229

Study results