Laser speckle contrast imaging, surgical eye and indocyanine green fluorescence imaging for perfusion assessment of the gastric conduit

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In this trial we will study the utility of PerfusiX-Imaging for perfusion assessment of the gastric conduit in comparison with the standard of care.

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

Summary

ID

NL-OMON51274

Source
ToetsingOnline

Brief title
Comparison of perfusion assessment techniques of the gastric conduit

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
Anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: LIMIS Development BV

Source(s) of monetary or material Support: LIMIS Development BV

Intervention

Keyword: gastric conduit, Laser speckle contrast imaging, perfusion assessment

Outcome measures

Primary outcome

All patients will undergo the standard-of-care program which includes perfusion assessment by the surgical eye and ICG-fluorescence imaging. In addition to this standard-of-care, 2D-perfusion maps will be generated from images taken with PerfusiX-Imaging (LIMIS Development BV, Leeuwarden, The Netherlands) in combination with a standard surgical laparoscope. Not related to the patient, the PerfusiX-Imaging images will be shown to the surgeon postoperatively and peroperative questionnaires will be filled regarding the standard-of-care perfusion assessment.

Study parameters/endpoints

Due to the explorative character of this study, there is no formal hierarchy in the respective endpoints of this study. In this, all endpoints will add to the overall assessment of the feasibility of the PerfusiX-imaging derived visual feedback. We will look at the percentage of operating surgeons that indicated no change in location of the anastomosis or operating plan based on the additional PerfusiX-Imaging. The percentage of the non-involved surgeons that indicated no change in location of the anastomosis or operating plan based on the additional PerfusiX-Imaging. The comparison will be made between these two groups by looking at the proportion of the indication of a change in location by operating and non-involved surgeons between patients with and without AL and

Perfusix-Imaging. And the homogeneity of the change in location between non-involved surgeons for individual patients will be analyzed in order to get a sense for the subjectivity of the interpretation of the images.
We will also compare the additional PerfusiX-Imaging derived visual feedback to the standard of care by looking at the homogeneity in location of the watershed area between PerfusiX-Imaging, ICG-fluorescence and based on visual assessment by the surgical eye. The difference in the location of watershed area between PerfusiX-Imaging and ICG-fluorescence or based on visual assessment.
In order to get a sense of the scale of the indicated change in location of the anastomosis we will look at the estimated change in location of the anastomosis of the gastric conduit/ the esophageal stump in centimeters by the operating surgeon. The estimated change in location of the anastomosis of the gastric conduit/ the esophageal stump in centimeters by non-involved surgeons. Lastly, we will compare the change in the location of the anastomosis by non-involved surgeons in comparison to the operating surgeon;

Secondary outcome

N/A

Study description

Background summary

Globally, esophageal cancer is the seventh most common cancer type, with over half a million cases reported in 2020. The survival of gastroesophageal cancer is poor and the prognosis is primarily determined by the possibilities for curative treatment. After resection of part of the esophagus and cardia, the

reconstruction of the esophagus is performed with a gastric conduit where an anastomosis is made with the proximal esophageal stump. Globally, a Minimally invasive Esophagectomy (MIE) has a high morbidity rate and a mortality rate ranging up to 5% as a result of the procedure. One of the most feared complications is an anastomotic leakage (AL) with a rate of around 12.5% and a mortality rate of around 15%. AL is associated with prolonged hospital stay and increased re-operation rates. It is generally accepted that impaired blood flow of the gastric conduit is the most important cause of AL. The surgical procedure of an esophagectomy and reconstruction inherently compromises the blood supply of the gastric conduit. However other than the surgical eye, there is no gold standard in assessing this. Surgeons generally look for traditional indicators of tissue viability such as pulsating vessels, bleeding of the resected edges, tissue color and intestinal motility. However, an objective indication of the tissue perfusion is still lacking, implying the clinical need for one.

Study objective

In this trial we will study the utility of PerfusiX-Imaging for perfusion assessment of the gastric conduit in comparison with the standard of care.

Study design

The current study is a prospective, observational single-center study in the Medical Center. All 30 patients will undergo the standard-of-care program which includes perfusion assessment by the surgical eye and ICG-fluorescence imaging. In addition to this standard-of-care, 2D-perfusion maps will be generated from images taken with PerfusiX-Imaging (LIMIS Development BV, Leeuwarden, The Netherlands) in combination with a standard surgical laparoscope. Not related to the patient, the PerfusiX-Imaging images will be shown to the surgeon postoperatively and peroperative questionnaires will be filled regarding the standard-of-care perfusion assessment.

Study burden and risks

The total surgery is expected to take 5 minutes longer. There are no known risks. Patients did not directly benefit from this study. The surgery proceeds as normal, with the addition of the additional perfusion measurements. During the operation, no decisions are made on the laser speckle images.

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

Scheduled to undergo esophageal resection

Exclusion criteria

Other interventions than esophageal resections

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2022
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	PerfusiX-Imaging
Registration:	No

Ethics review

Approved WMO

Date:	01-08-2022
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL81217.099.22