Efficiency, safety and feasibility of PerfusiX-Imaging for Gastro-Intestinal tissue perfusion assessment in humans.

Published: 21-12-2023
Last updated: 07-04-2024

The study objective is to evaluate the efficiency of PerfusiX-Imaging compared to the current state of the art for perfusion measurements; indocyanine green fluorescence imaging. Also, feasibility and safety of PerfusiX-Imaging for perfusion...

Ethical review	Not approved
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON56496

Source
ToetsingOnline

Brief title
SCOUT-II

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

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: gastrointestinal, Laser speckle contrast imaging, perfusion

Outcome measures

Primary outcome

- Efficiency of PerfusiX-imaging compared indocyanine green fluorescence imaging for intestinal perfusion imaging.

Secondary outcome

- Incidence of any adverse event (adverse events will be summarized descriptively and formulations on the type, severity and relationship with regards to the device will be performed)
- We will assess the feasibility by monitoring the technically successful completion of intended perfusion visualization. The ability of PerfusiX-Imaging to display perfusion (yes/no)
- Usability of Perfusix-Imaging (ease of setup, latency of display, quality of perfusion display, concordance/discordance with surgical eye-based/ICG-based assessments, support personnel satisfaction).
- Related patient information will be recorded (height, weight, BMI, HB-value, blood pressure and heart rate during imaging procedures)

Study description

Background summary

Any gastrointestinal resection causes inevitable vascular damage, which is not always evident during an intraoperative clinical assessment of local intestinal perfusion. However, if left unaltered, impaired perfusion can lead to anastomotic healing complications such as anastomotic leakage (AL). Owing to

its detrimental effect on both short and long-term outcomes (e.g., increased 30-day mortality risk, worsened oncological prognosis), AL is also one of the most severe possible complications of gastrointestinal tract surgery. A significant percentage of patients undergoing restorative intestinal surgery develop AL, leading to both considerable morbidity and mortality. Impaired perfusion is one of the key factors implicated in anastomotic failure. Ensuring adequate perfusion is an important part of a multidimensional approach to gradually improving the overall outcome in restorative intestinal surgery. Thus, there is a need for an objective measure of perfusion suitable for laparoscopic use.
Today, the most commonly used method for the assessment of tissue perfusion for the gastrointestinal tract (and in general) is the mere simple inspection using the surgical eye. However, it is hard to objectify and the judgement is heavily dependent on the surgeons* experience. More recently, ICG-fluorescence imaging was introduced in the surgical theater for the visualization of gastrointestinal blood flow. Unfortunately, this approach is suboptimal in effectiveness (Non-flowing blood containing ICG gives the same signal as flowing blood containing ICG (i.e., lacks objectivity and specificity for flowing blood)) and it is cumbersome to efficient workflow (need for contrast agent, reagent preparation and injection, potential adverse allergic reactions). The use of a dye limits the user in perfusion visualization duration, repetitiveness and introduces a lack-time between the need for perfusion visualization and the actual visualization.
PerfusiX-Imaging is a dye-free method that could simplify, and thus speed up, objective intraoperative perfusion assessment. The device is added to the laparoscopic trolley and thereby is able to upgrade any laparoscopic video system with perfusion imaging possibilities. In comparison to the current clinical practice of gastrointestinal tissue visualization, based on the mere visual inspection by human eye or the cumbersome ICG-based systems, our hypothesis is that PerfusiX-Imaging delivers safe, precise, objective and real-time visualization of blood flow and tissue perfusion intraoperatively during minimally invasive surgery with the following benefits:
1) Quantitative images: PerfusiX-Imaging is based on the LSCI technology and thus provides objective information related to tissue perfusion
2) No contrast agent: PerfusiX-Imaging does not require the use of a contrast agent. This means the surgeon can visualize perfusion at any time during surgery, for as long as required and with as many repetitive measurements are deemed necessary.
3) Real-time: PerfusiX-Imaging will visualize the tissue perfusion in real-time. This allows the surgeon to manipulate tissue (e.g., clamping blood vessels) and visualize the effect on tissue perfusion directly. (i.e., this is not possible using current technologies)
4) Lower patient risk: The risk of adverse events related to the injection of contrast agents is eliminated associated with comparable imaging systems, as PerfusiX-Imaging does not require a contrast agent
5) Usability: PerfusiX-Imaging will visualize tissue perfusion in real-time without the interruption of the workflow as the visualization is ready at the

press of a button.

Study objective

The study objective is to evaluate the efficiency of PerfusiX-Imaging compared to the current state of the art for perfusion measurements; indocyanine green fluorescence imaging. Also, feasibility and safety of PerfusiX-Imaging for perfusion visualization of gastrointestinal anastomoses. The safety will be determined through clinical assessments and evaluation of any adverse event. The feasibility will be determined through the technically successful completion of the perfusion visualization. Patients will be in a follow-up to 30 days postoperatively monitored for the clinical outcome.

Study design

The current study is a single-center, randomized, intervention study in the Medical Center Leeuwarden.

Intervention

All patients will undergo the standard-of-care program which includes perfusion assessment by the surgical eye. In addition to this standard-of-care, 2D-perfusion maps will be generated of the gastrointestinal perfusion before the creation of the gastrointestinal anastomoses using PerfusiX-Imaging perfusion mode in combination with a proprietary third-party surgical laparoscope or using ICG-fluorescence imaging depending on group allotment.

Study burden and risks

Burden
The surgical procedure will be extended by a short amount of time (<5 min).

Risks
PerfusiX-Imaging poses non-significant low safety concerns based on the fact that the device has no patient contact with a very low laser output.

Benefit
The proposed trial poses minimal risk and maximum potential benefits for perfusion imaging of the gastrointestinal tract thereby aiding in better substantiated clinical decision making.

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

All patients with a clinical suspicion and diagnosis of benign or malignant, small or large bowel lesions requiring surgical resection and any bariatric patients undergoing bypass surgery (Roux-en-Y gastric bypass).

Exclusion criteria

No vulnerable population will be included in this investigation.
- Medical or psychiatric conditions that compromise the patient*s ability to give informed consent;
- Breastfeeding or pregnant population

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2023
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	PerfusiX-Imaging
Registration:	No

Ethics review

Not approved

Date:	18-12-2023
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	NL83910.000.23
Other	TBD