Feasibility of laser speckle contrast imaging using the bowel perfusion assessment tool Lapvas-Imaging

Gepubliceerd: 19-01-2021 Laatst bijgewerkt: 18-08-2022

the current intraoperative selection of an optimal site for the anastomosis is based on subjective clinical indicators of intestinal viability. As indicated by others there is a need for a gold standard in determining the state of microcirculation...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25695

Bron
Nationaal Trial Register

Verkorte titel
SCOUT-I

Aandoening

Colorectal cancer

Ondersteuning

Primaire sponsor: LIMIS Development B.V.
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- The percentage of operating surgeons that indicated no change in location of the anastomosis based on the additional Lapvas-Imaging derived visual feedback;
- The percentage of the non-involved surgeons that indicated no change in location of the anastomosis based on the additional Lapvas-Imaging derived visual feedback;
- The proportion of the indication of a change in location by operating and non-involved surgeons between patients with and without AL;
- The homogeneity of the change in location between non-involved surgeons for individual patients;
- The estimated change in location of the anastomosis proximal/distal in centimeters by the treating surgeon;
- The estimated change in location of the anastomosis proximal/distal in centimeters by non-involved surgeons;
- A change in the location of the anastomosis by non-involved surgeons in comparison to the operating surgeon;
- Development of anastomotic leakage;
- Extra time taken for imaging during surgery (seconds);

Toelichting onderzoek

Achtergrond van het onderzoek

For colorectal cancer, the third most commonly occurring malignancy worldwide, surgery remains the primary therapeutic modality. However, anastomotic leakage (AL) is a major problem in gastrointestinal surgery. The general consensus is that an important factor regarding AL is the state of microcirculation at the site of the anastomosis. It is expected that a better state of microcirculation contributes to a fast healing process which in term leads to a lower incidence of AL. Lapvas-Imaging is contactless, dye-free real time perfusion imaging tool that gives insight in the state of perfusion of live tissue during laparoscopic surgery. The overall objective of this study is to determine whether the use of additional Lapvas-imaging derived visual feedback might influence the choice of surgeons for the optimal location of the anastomosis.

Doel van het onderzoek

the current intraoperative selection of an optimal site for the anastomosis is based on subjective clinical indicators of intestinal viability. As indicated by others there is a need for a gold standard in determining the state of microcirculation of the intestines. This method should be suitable for laparoscopic use, robust and preferably non-invasive. Using Lapvas-Imaging, real-time feedback can be obtained and used for clinical decision-making during surgery, which might be beneficial to the patient. In this prospective observational feasibility study, we aim to determine whether surgeons would choose a different location for the original anastomosis, based on additional Lapvas-imaging derived visual feedback

Onderzoeksopzet

Images will be acquired during surgery using Lapvas-Imaging before the surgeon dissects the (1) proximal and (2) distal end of the anastomosis. The surgeons will subsequently be questioned using these images.

Contactpersonen

Publiek

University of Groningen
Wido Heeman

--

Wetenschappelijk

University of Groningen
Wido Heeman

--

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, the subject must meet all following criteria:
- Confirmed colorectal cancer and scheduled to undergo surgical resection;
- Age > 18 years;
- Written informed consent;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Medical or psychiatric conditions that compromise the patient’s ability to give informed consent;
- Concurrent uncontrolled medical conditions;
- Elected for subtotal colectomy;
- Elected for abdominoperineal resection;
- Elected for temporary colostomy procedures;

- Septic patients;
- Non-elective surgery;

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	67
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9215
Ander register	RTPO : RTPO1102

Resultaten