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

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The overall objective of this study is to determine whether the use of additional Lapvasimaging derived visual feedback might influence the choice of surgeons for the optimal location of the anastomosis.

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

# Summary

### ID

NL-OMON54884

**Source** ToetsingOnline

Brief title SCOUT-I

### 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

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#### Intervention

Keyword: Anastomotic leakage, Lapvas-Imaging, Laser speckle contrast imaging

#### **Outcome measures**

#### **Primary outcome**

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);

#### Secondary outcome

N/A

# **Study description**

#### **Background summary**

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 A recent large Dutch cohort study reported an AL incidence of 8.4%. The persistence of this complication over the last decades is partly caused by its multi-factorial origin. 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 investigation medical device is based on a technique called laser speckle contrast imaging (LSCI). It uses the current standard of care laparoscopic video equipment.

#### **Study objective**

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.

#### Study design

The current study is a prospective, observational study. A total of 67 patients undergoing an oncological colorectal resection will be included. 2D-perfusion maps will be generated from images taken with Lapvas-Imaging (LIMIS Development BV, Leeuwarden, The Netherlands) in combination with a standard surgical laparoscope and video system (EndoEye, Olympus Medical, Hamburg, Germany) during surgery at the moment before the creation of the proximal and distal anastomosis. The images will be shown to the surgeon postoperatively.

#### Study burden and risks

Time during surgery: The surgery will take up around 2 minutes more. There are no known risks to study participants. Patients will have no benefit from this study directly. Surgery will be planned as usual. During surgery, no decisions will be made based on Lapvas-Imaging.

# Contacts

Public LIMIS Development BV

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

Confirmed diagnosis of colorectal cancer and are scheduled to undergo surgical resection (Hemicolectomy right, hemicolectomy left and sigmoid resection)

### **Exclusion criteria**

Subtotal colectomy, abdominoperineal resection, temporary colostomy procedures, septic patients, non-elective surgery

# Study design

# Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2021
Enrollment:	67
Туре:	Actual

# Medical products/devices used

Generic name:	Lapvas-Imaging
Registration:	No

# **Ethics review**

Approved WMO	
Date:	04-01-2021
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	15-04-2021
Application type:	Amendment
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 CCMO **ID** NL74681.099.20