Intraoperative assessment of microcirculation with Laparoscopic Laser Speckle Analysis (lapLASCA) in patients elected for colorectal surgery for prediction of anastomotic leakage in colorectal anastomoses.

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Experimentally, develop a software algorithm to objectively assess the microcirculation quality of the colorectal wall, intraoperative, by laparoscopy to predict the probability of developing anastomotic leakage, with the intention to develop a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON44223

Source
ToetsingOnline

Brief title
LapLASCA research

Condition

- Gastrointestinal infections
- Gastrointestinal therapeutic procedures

Synonym
Anastomotic leakage, suture leakage

Research involving
Human

Sponsors and support

Primary sponsor: LIMIS
Source(s) of monetary or material Support: Door SNN Operationeel programma Noord-Nederland;bestaande uit Rijkscofinanciering en OP/EFRO. Overige cofinanciering door Provincie Fryslan;gemeente Leeuwarden;Medisch Centrum Leeuwarden en de Friesland Zorgverzekeraar

Intervention

Keyword: Anastomotic leakage, colorectal, laparoscopy, microcirculation

Outcome measures

Primary outcome

1. The mean speckle contrast, intraoperative, of the colon or rectum in

patients, with 532nm and 660nm light, who have developed anastomotic leakage

2. The mean microcirculatory flow, intraoperative, of the colon or rectum in

patients, with 532nm and 660nm light, who have developed anastomotic leakage

3. The mean speckle contrast, intraoperative, of the colon or rectum in

patients, with 532nm and 660nm light, who have not developed anastomotic leakage

4. The mean microcirculatory flow, intraoperative, of the colon or rectum in

patients, with 532nm and 660nm light, who have not developed anastomotic leakage

All 4 primary parameters are measured during the folowing critical moments

during elected colorectal surgery:

a. Before vascular ligation (baseline):

b. At a reference, coecum or sigmoid (baseline)

c. After vascular ligation

d. After colon division at the proximal and distal stump

e. On the anastomosis

Secondary outcome

All other riskfactors related to anastomotic literature found in literature

Study description

Background summary

Anastomotic leakage (AL) is the commonest major complication in colorectal surgery, the resection of a part or entire colon or rectum, due to the presence of cancer or diverticulitis. The consequence of AL is that intestinal contents (faeces) are entering the abdominal cavity, which can lead to peritonitis and can result in the need for additional surgery, prolonged hospital stays, increased morbidity and mortality and possibly a poorer oncological prognosis in the postoperative period.

In literature, different percentages are published about the occurrence of AL varying from 0.5%-30%, depending on the method of evaluation and location of the anastomosis, with an associated 30-day mortality rate of 3%-22% with subsequently a 10%-100% chance of permanent stoma. The current average AL rate in The Netherlands is 11%.

The mean length of stay in the hospital for patients with anastomotic leakage has been described between 36 and 39 days, approximately 4 times longer than for patients without a leak. This prolonged hospital stay is caused by multiple reoperations and stoma creation to control the leak, which significantly increases health risks and healthcare costs up to 5 times that of patient without a leak.

Study objective

Experimentally, develop a software algorithm to objectively assess the microcirculation quality of the colorectal wall, intraoperative, by laparoscopy to predict the probability of developing anastomotic leakage, with the intention to develop a novel diagnostic device based on a laparoscopic laser speckle contrast analysis (lapLASCA) technique.

Study design

The research is done during elected colorectal surgeries. At critical moments

during surgery, videos are captured with red (660nm) and green (532nm) light, instead of the normally used white light. During each video a reference video will be recorded of the coecum or sigmoid (dependent of the type of resection surgery). These videos are stored and post-operatively processed with a software algoritm (lapLASCA) for further analysis. The quality of the microcirculation can be determined by contrast or flow differences, intra-individual or over the population. In combination with other anastomotic leakage risk factors, a analysis will be done to study the possibility to use lapLASCA in a medical device to predict the probability of anastomotic leakage occurrence, postoperative to colorectal surgery.

Study burden and risks

Patient risk will be minimal. Possible risks for the patients are prolonged surgeries, caused by the videocapturing (>200 minutes is related to increased risk for anastomotic leakage, 180 minutes is normally scheduled for these type of surgeries). Air flow can be changed, caused by positioning of the research equipment and/or more people in OR. This can increase the risk of developing wound infections.

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

- elected surgery
- right (extended) hemicolectomie
-transverse colectomy
- sigmoid colectomy
- (low) anterior rectal resection
- Hartmann reversal surgery
-Laparoscopic procedure

Exclusion criteria

* Elected for subtotal colectomy
* Elected for abdominoperineal resection
* Elected for temporary colostomy procedures
* Septic patients (anastomotic leakage)
* Emergency surgeries

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-11-2015

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2014
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	09-03-2015
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-04-2016
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	ID
CCMO	NL47924.099.14