Anastomotic Perfusion Measuring Device, a Pilot Trial

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We want to show in the current pilot trial that the current market ready automated device is safe and effective to use in humans as the proof of principle prototype, as well as check the instructions for use (IFU).

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON49771

Source
ToetsingOnline

Brief title
APM study

Condition

- Gastrointestinal conditions NEC

Synonym
Anastomotic leakage

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: bedrijf,Corporis Medical (Health Value creation)

Intervention

Keyword: Anastomotic leakage, Colorectal surgery, Perfusion Measuring device

Outcome measures

Primary outcome

1. Time needed to measure bowel-brachial index

2. Percentage of successful bowel-brachial index measurements, the percentage needs to be 90% or higher. The APM device needs to display and index and not display an error message. It will be allowed to try multiple times per patient.

3. Safety of the product will be defined as that no adverse events related to the APM measurement are observed.

Secondary outcome

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Study description

Background summary

Anastomotic leakage remains a serious complication following colorectal surgery. Its reported prevalence varies widely from 1% to 39%. Not only may the complication result in an acute life-threatening condition, cancer patients show a higher local recurrence rate following anastomotic complications with local abscess formation. Anastomotic complications are thought to be related to an inadequate perfusion of the anastomosis]. Currently, viability of the bowel, before performing the anastomosis, is usually estimated by the color of the tissue. This remains very subjective and based on the experience of the surgeon.

Study objective

We want to show in the current pilot trial that the current market ready automated device is safe and effective to use in humans as the proof of principle prototype, as well as check the instructions for use (IFU).

Study design

Prospective PILOT trial
In the surgical outdoor clinic patients will be asked by their treating surgeon whether they wish to take part in the trial. If informed consent is obtained (and the patient meets all the inclusion and exclusion criteria as described in paragraph 9) the patient will be included in the trial. Patients will undergo elective colorectal surgery. The operating surgeon will measure the bowel-brachial index at the site of anastomosis with the APM device.

Study burden and risks

No substantial risk or burden is anticipated for patients participating in this study. The prototype prior to the current market ready device has been used before in 215 patients without adverse events. To detect blood pressure in the bowel wall, the device only applies mild pressure on the bowel wall for short period of time. The systemic blood pressure is measured by standard NIBP (non-invasive blood pressure) module.

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

Oral and written informed consent (IC)
Age 18 years and older
Elective colorectal surgery

Exclusion criteria

-No informed consent
-Palliative surgery
-Emergency surgery
-Mental handicap

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2020
Enrollment:	12
Type:	Anticipated

Medical products/devices used

Generic name:	Anastomotic Perfusion Measuring Device
Registration:	No

Ethics review

Approved WMO Date:	17-06-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL72472.068.19
Other	tbd