

Imaging Microcirculation And Gross hemodynamic assessment of the bowel during Elective colorectal Surgery

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To describe the human gastrointestinal microcirculation during gastrointestinal surgery under general anesthesia and to observe whether there is a correlation between bowel microcirculation and systemic hemodynamic parameters.

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

Summary

ID

NL-OMON42295

Source

ToetsingOnline

Brief title

IMAGES

Condition

- Gastrointestinal therapeutic procedures

Synonym

gastrointestinal microcirculation, gastrointestinal microvascularisation

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dark Field imaging, gastrointestinal surgery, hemodynamics, microcirculation

Outcome measures

Primary outcome

To describe human gastrointestinal microcirculation on both the serosal and mucosal side of the bowel during gastrointestinal surgery under general anesthesia. Main parameter: Microvascular perfusion is quantified using the Microvascular Flow Index (MFI).

Secondary outcome

Perfused vessel density (PVD), proportion of perfused vessels (PPVs), en heterogeneity of the microcirculation. To observe the possible correlation between bowel microcirculation and systemic hemodynamic parameters. MFI, PVD, PPV and indices of heterogeneity are compared between sides and to systemic hemodynamic parameters such as blood pressure, and if accessible, cardiac output (CO), stroke volume (SV) and stroke volume variation (SVV). These latter parameters are automatically measured by the FloTrac*/Vigileo* and thus only accessible when an arterial catheter is inserted.

Study description

Background summary

The interaction between macro and microcirculation remains uncertain. Microvascular alterations can occur when systemic hemodynamic parameters are within an acceptable range. Perfusion changes and microvascular alterations may play an important role in anastomotic healing and the onset of anastomotic leakage after gastrointestinal surgery. Nowadays, assessment of bowel perfusion is macroscopically performed by the surgeon prior to anastomosis creation.

However, local oxygen delivery may still be compromised as little is known about microcirculatory alterations of the bowel during colorectal surgery. Dark Field (DF) imaging is a technique using a stroboscopic light-emitting diode ring-based imaging modality incorporated in a hand-held device, which illuminates an area of interest and provides high contrast dynamic images of the microvasculature. DF-imaging enables to visualize the bowel's microcirculation.

Study objective

To describe the human gastrointestinal microcirculation during gastrointestinal surgery under general anesthesia and to observe whether there is a correlation between bowel microcirculation and systemic hemodynamic parameters.

Study design

A prospective, single center, observational, clinical, pilot study.

Study burden and risks

The extend of burden and risk associated with participation is negligible. Using DF imaging on the bowel is a non-invasive technique requiring a minimal amount of time as is described in the study procedure. Previous studies did not show any safety concerns. Measuring will be performed under sterile conditions and the occurrence of tissue damage is highly unlikely. Patients are under general anesthesia and will thus not experience any inconvenience.

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 aged >18 scheduled for elective, gastrointestinal surgery (as described above) with signed informed consent.

Exclusion criteria

Age <18 years;

Atrial fibrillation (because of possible interference with FloTrac*/Vigileo* cardiac output monitor);

Left ventricular ejection fraction <30%;

Serious pulmonary disease (resting pO₂ <90% at room air);

Renal failure (clearance <30 ml/min as calculated using the Modification of Diet in Renal Disease formula);

Liver failure;

No signed informed consent.

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): 27-05-2014
Enrollment: 70
Type: Actual

Medical products/devices used

Generic name: Sidestream Dark Field (SDF) and cytocam-Incident Dark Field (IDF) imaging devices: video microscope
Registration: Yes - CE outside intended use

Ethics review

Approved WMO
Date: 06-05-2014
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 21-12-2015
Application type: Amendment
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

NL48332.100.14