

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

Published: 06-05-2014

Last updated: 20-04-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal therapeutic procedures
<b>Study type</b>	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 pO<sub>2</sub> <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