skin autofluorescense in patients undergoing elective colorectal surgery.

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To determine if there is an increase of skin-autofluorescense in subjects undergoing elective colorectal surgery.

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

Summary

ID

NL-OMON32368

Source ToetsingOnline

Brief title Skin autofluorescence in elective colorectal surgery

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym anastomotic leakage, complications

Research involving Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Stichting Wetenschap Maatschap Chirurgie Isala Klinieken

Intervention

Keyword: autofluorescense, colorectal, complications, surgery

Outcome measures

Primary outcome

Skin autofluorescense after elective colorectal surgery

Secondary outcome

Infection parameters after elective colorectal surgery

Study description

Background summary

Laparotomy causes oxidative stress in the gut because of an increase in xanthine oxidase, decreased antioxidant status of the gut and a change in mitochondrial funtioning of enterocytes. Inflammation and ischemia-reperfusion effects also attribute to this oxidative stress. As a consequence there are both local and systemic effects notable. Ischemia-reperfusion effects are normal in any laparotomy, thus not only when bloodvessels are clamped. Splanchnic vasoconstriction happens during hypovolemia, epidural anesthesia and manipulation of the gut. This local ischemia-reperfusion causes an enhanced permeability of the gut, sepsis and a increased systemic inflammatory response. Local increase in oxidative stress has shown to be related to a higher chance of anastomotic leakage in animal models. The systemic response to this ischemia-reperfusion effect leads to an increased rate of cardiopulmonary complications.

Different methods can be used to detect oxidative stress. One of these is autofluorescence of the skin. An increased autofluorescense of the skin caused by oxidative stress is already shown in acute coronary events and sepsis. Autofluorescense is not only a marker of oxidative stress but it also increases when Advancced Glycation Endproducts (AGEs) are being formed. AGEs are formed through biochemical reactions of glucose, lipids, proteins and oxidative stress. Therefore skin autofluorescense is an indicator of cumulative metabolic stress. AGEs are related to the genesis of a broad spectrum of systemic complications such as atherosclerosis, renal failure and M. Alzheimer. AGEs are able to predict cardiovascular morbidity and mortality. Simm et al have shown that the level of preoperative AGEs is a predictor of per-operative occurrence of complications and length of stay in the intensive care unit. One could assume that the amount of AGEs is related to the vitality of a patient.

Study objective

To determine if there is an increase of skin-autofluorescense in subjects undergoing elective colorectal surgery.

Study design

This study will be an observational pilot study in the Isala Clinics Zwolle. 75 patients undergoing elective colorectal surgery will be included in the study. Pre- and post-operative autofluorescense (AFR)-measurement of the skin will be done. Also patient characteristics (eg indication, comorbidities) will be looked at. Details of surgery will be noted too, like length of operation, blood loss, diuresis, saturation, blood pressure and preoperative complications. Besides the AFR-measurement CRP, leucocytes, kreatinine, glucose, NK-cells, vital functions, diuresis, length of ileus and complications will be noted too. In the Isala Clinics these data can be collected through the already existing colorectal database. After including 75 patients we will analyse the data in order to specify our hypothesis.

Study burden and risks

The autofluorescense measurement will be done daily. The meaurement will cost 5 minutes of a patients time and is non-invasive. Also patients don't need to be transported because the measurement can be done anywhere. The vena-punction will be one every other day. Undergoing these vena-punctions comprises the usual burden/risks: pain, tromboflebitis, hematoma.

Contacts

Public Isala Klinieken

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing elective colorectal surgery

Exclusion criteria

Patients younger than 18, acute colorectal surgery

Study design

Design

Study type: Observational invasive		
Masking: Open (masking n		
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	75
Туре:	Actual

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Ethics review

Approved WMO Date: Application type: Review commission:

14-07-2008 First submission METC Isala Klinieken (Zwolle)

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 NL22340.075.08