Stimulation of the autonomic nervous system to improve postoperative recovery after colorectal surgery

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To study the occurrence of postoperative ileus and the extend of the postoperative inflammatory response either systemic as well as locally in the bowel in patients receiving chewing gum before and after colorectal surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON32885

Source
ToetsingOnline

Brief title
SANICS

Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym
postoperative ileus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Autonomic nervous system, Colorectal surgery, Ileus, Inflammation

Outcome measures

Primary outcome

Length of hospital stay, occurrence of postoperative ileus.

Secondary outcome

Inflammatory cytokines and acute phase proteins (TNF-alpha, IL-6, CRP).

Mediators of the inflammatory response in bowel tissue. Expression of nitric oxide synthases and their precursor arginine in plasma. The effect on tissue damage in the bowel, specified by measuring tissue damage markers in plasma and specifying bowel damage in the removed specimens and 24h-urine. Morbidity and mortality.

Study description

Background summary

We hypothesized that stimulation of the autonomic nervos system via de vagal nerve reduces the postoperative inflammatory response after colorectal surgery. In this way, complications such as postoperative ileus will be reduced and recovery after surgery is enhanced. Experimental studies already showed that vagal nerve stimulation reduces postoperative ileus and decreases the inflammatory response following hemorrhagic shock, endotoxemia and ischemia/ reperfusion. Stimulation of the autonomic nervous system releases acetylcholine that binds to nictotinic receptors located on inflammatory cells. Hereby, production of inflammatory mediators is directly inhibited. It is thought that the chewing of gum activates the autonomic nervous system vai de vagus nerve.

Study objective

To study the occurrence of postoperative ileus and the extend of the postoperative inflammatory response either systemic as well as locally in the

bowel in patients receiving chewing gum before and after colorectal surgery.

Study design

A prospective, randomized controlled trial

Intervention

Patients in this study will be divided into two groups. Group one will receive chewing gum three hours preoperatively until time of surgery. Three hours postoperatively chewing gum will be distributed again to the patients until the start of enteral nutrition. All patients in group two, the placebo controlled group, will receive a dermal patch three hours preoperatively. This dermal patch will be removed until the first moment of oral nutrition is achieved. Preoperatively the vagal activity of all patients will be measured by variation of the heartbeat via blood pressure measurements, electrocardiographs and impedance cardiographs.

Study burden and risks

Patients included in this study will be seen one extra time at the outpatient clinic. There will be taken 10 ml extra venous blood preoperatively additional to the regular blood samples. There will be a vagal activity measurement by use of electrocardiography and blood pressure measurements. These measurements are without any known health risks, non invasive en take about one hour in total. Biopsy will be done from the removed bowel to assess bowel damage. This causes no extra inconvenience or risk for the patients. In the postoperative phase blood samples (in total 36 ml) will be collected at six different time-points till 48 hours postoperatively from an intravenous line, that is standard for this kind of surgery. The collected amount of blood is not much and patients have besides the vena puncture no other discomfort.

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

1. Colorectal neoplasm selected for surgery.
2. Age > 18.

Exclusion criteria

1 Previous gastric resection or esophagus resection
2 Disturbance of acetylcholine metabolism in neurologic disease
3 Usage of selective serotonin re-uptake inhibitors (SSRI)
4 Depression
5 Inflammatory bowel disease
6 Drugs influencing bowel motility
7 Mint allergy
8 Metastatic spreading disease
9 Stoma

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2009
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2008
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL25588.096.08