Stimulation of the autonomic nervous system in colorectal surgery by perioperative nutrition

Published: 15-11-2013
Last updated: 19-03-2025

The main objective is to investigate the effects of perioperative nutrition on postoperative ileus and anastomotic leakage in patients undergoing colorectal surgery

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON41286

Source
ToetsingOnline

Brief title
Perioperative nutrition in colorectal surgery

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
lekkage van de darmaansluiting, verlamming van de darm

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Danone Research;Fonds Nuts Ohra

Intervention

Keyword: anastomotic leakage, autonomic nervous system, colorectal surgery, perioperative nutrition

Outcome measures

Primary outcome

Main clinical outcome parameter is postoperative ileus.

Secondary outcome

- Anastomotic leakage

- Aspiration pneumonia

- Gastric volumes preoperatively

- Length of functional recovery

- The local and systemic inflammatory response

- Surgical complications

- Length of stay

- Intestinal barrier function and local inflammation in the gut

- Need for additional surgical, radiological or endoscopic interventions

- Need for ICU admission and total length of ICU stay

- micriobiota in feces pre and postoperatively

- Quality of life (EQ-5D and EORTC-QLQ-C30 at baseline, after 3 and 6 months)

Study description

Background summary

Postoperative ileus and anastomotic leakage are complications associated with short-term morbidity and mortality following colorectal surgery. Based on experimental studies, we hypothesize that enriched enteral nutrition shortly

before, during and early after colorectal surgery reduces inflammation by stimulation of the autonomic nervous system and thereby postoperative ileus (POI) and anastomotic leakage.

Study objective

The main objective is to investigate the effects of perioperative nutrition on postoperative ileus and anastomotic leakage in patients undergoing colorectal surgery

Study design

A prospective double-blind randomized controlled trial

Intervention

Perioperative nutrition via a nasojejunal tube

Study burden and risks

Patients allocated in both groups receive a selfmigrating nasojejunal tube one day before surgery. The position of the tube is checked via X-ray the same day. Blood samples will be collected at several predefined moments in relation to the moment of incision. Furthermore, gastric emptying will be assessed via ultrasound as previously performed in another protocol in the Catharina Hospital (SANICS trial M11-1102, CCMO NL25588.096.08). This intervention may benefit the patient by reducing postoperative complications and enhancement of recovery.
Peritoneal lavage is performed at the start of surgery and at the end of surgery. Also gastric content is measured during surgery. It is expected that these procedures will be no burden for the patient.

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

- patients that undergo colorectal surgery with primary anastomosis
- written informed consent
- age above 18 years

Exclusion criteria

- use of medication that disrupts acetylcholine metabolism
- steroid use
- previous gastric or esophageal resection
- peritoneal metastases found during surgery
- pre-existent or creation of an ileostomy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-07-2014
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-10-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-05-2015
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

ID: 20551
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02175979
CCMO	NL45640.060.13
OMON	NL-OMON20551