Stimuleren van het onwillekeurige zenuwstelsel met perioperatieve voeding bij patiënten die een darmoperatie ondergaan.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20551

Source
Nationaal Trial Register

Brief title
SANICS II

Health condition

Postoperative ileus, anastomotic leakage, colorectal surgery, enteral nutrition, intestinal damage, inflammation

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven
Source(s) of monetary or material Support: ZonMW
Danone/Nutricia

Intervention

Outcome measures

Primary outcome

1. Postoperative ileus

Secondary outcome

1. Aspiration pneumonia

2. Preoperative gastric volumes

3. Length of functional recovery

4. Length of stay

5. The local and systemic inflammatory response

6. Intestinal barrier integrity

7. Surgical complications according to Clavien-Dindo

8. Need for additional surgical, radiological or endoscopic interventions

9. Need for ICU admission and total length of ICU stay

10. Health related quality of life
11. Anastomotic leakage
12. Cost effectiveness ratios

Study description

Background summary

Postoperative ileus (POI) and anastomotic leakage (AL) are important complications following colorectal surgery associated with short-term morbidity and mortality. Previous experimental and preclinical studies have shown that a short intervention with enriched enteral nutrition dampens inflammation via stimulation of the autonomic nervous system and thereby reduces POI. Furthermore, early administration of enteral nutrition after surgery reduced AL. This study investigates the effect of nutritional stimulation of the autonomic nervous system just before, during and after surgery on inflammation, POI and AL.

This multicentre, prospective, double blind, randomised controlled trial will include 280 patients undergoing colorectal surgery. All patients receive a selfmigrating nasojejunal tube that will be connected to a custom-made blinded tubing. Subsequently, patients are allocated to either the intervention group, receiving perioperative nutrition or to the control group,

receiving no nutrition. Primary endpoints are POI and AL. Secondary endpoints are local and systemic inflammation, (aspiration) pneumonia, surgical complications classified according to Clavien-Dindo, quality of life, gut barrier integrity and length of functional recovery. Furthermore, a cost-effectiveness analysis will be performed.

Activation of the autonomic nervous system via perioperative enteral feeding is expected to dampen the local and systemic inflammatory response. Consequently, POI will be reduced as well as AL. The present study is the first to investigate the effects of enriched nutrition given shortly before, during and after surgery in a clinical setting.

Study objective

Giving perioperative lipid-enriched nutrition in colorectal surgery stimulates the autonomic nervous system leading to an anti-inflammatory effect. This will lead to a decrease in postoperative ileus and anastomotic leakage.

Study design

1. Postoperative ileus: within 1 week after surgery by daily control of clinical parameters, and rate of gastric emptying at postoperative day 2.

2. Anastomotic leakage: within 6 weeks after surgery by clinical/radiological signs or confirmed by reoperation.

3. Inflammatory response: bloodsamples: preoperatively, 4-24-48hours postoperatively, tissue sample and peritoneal lavage sample during surgery.

4. Quality of life: preoperatively, 3 months, 6 months

Intervention

All patients receive a selfmigrating nasojejunal tube. Via a custom-made tubing system blinding will be ensured.
Intervention group: patients will receive enriched enteral nutrition from 3 hours prior to surgery, until 6 hours after surgery.

Control group: patients will not receive nutrition, but via the special tubing, the nutrition will be collected in a bedside-container instead.

Contacts

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Eligibility criteria

Inclusion criteria

1. Elective segmental colorectal resection with primary anastomosis

2. Written informed consent

3. Age >18 years

Exclusion criteria

1. Previous gastric or oesophageal resection

2. Pre-existent or creation of ileostoma

3. Steroid use

4. Use of medication that disrupts acetylcholine metabolism (SSRI’s or anticonvulsants)

5. Peritoneal metastases

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2014
Enrollment:	280
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-07-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41286
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4494
NTR-old	NTR4670
CCMO	NL45640.060.13
OMON	NL-OMON41286

Study results