Enteral Nutritional strategies compared to reduce postoperative ileus after major colorectal surgery

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

Summary

ID

NL-OMON30037

Source
ToetsingOnline

Brief title
ENRI-Study afkorting van Enteral Nutrition to Reduce Ileus

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
nutritional state, postoperative ileus, time of discharge

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: eigen studie;Catharina ziekenhuis

Intervention

Keyword: Bengmark, Early nutrition, Postoperatieve ileus

Outcome measures

Primary outcome

Postoperative ileus (duration in days)

Secondary outcome

Nutritional status will be measured using weight and bio-impendence

measurements (Body stat).

Complications

Lenght of hospitalisation

Amino acid profiles

Glucose metabolism: bij glucose, insuline and HbA1c

Study description

Background summary

Nutritional problems are common in hospitalized surgical patients, high percentages of patients undergoing colorectal surgery become more malnourished while hospitalized. Patients with malnutrition tend to stay longer in the hospital with increased costs and more infectious complications.
Numerous studies show that early enteral nutrition leads to better clinical outcome . Unfortunately no solid evidence until now has established clear evidence based on nutritional guidelines for this specific group of patients.

Study objective

The main objective of this clinical survey is to improve the nutritional status of patients undergoing major rectal surgery, thereby aiming to reduce postoperative ileus using the Bengmark a self-migrating nasojejunal tube and

early enteral nutritional strategies.

Study design

Open, randomized study, Catharina hospital, Eindhoven

Group 1: Oral challenge (conventional nutritional regime)
Group 2: early enteral nutrition starting 8 hours postoperatively, the same day as
surgery.
Group 3: Late enteral nutrition starting 16 hours postoperatively, the morning after surgery.

Group 2 and 3 will receive early nutrition via naso-jejunal tube (Bengmark) to overcome the delayed gastric motility and will be compared with group 1.

There will be 3 research visits, weight and nutritional state will be measured at day of admission, day after surgery and one week after surgery.
At these days also (extra) blood will be taken (total of 15 cc) and the BIA measurements will be done. Thereby eventually clinical complications and length of hospitalization will be reported.

BIA measuring is an easy and totaly not invasive measurement. While patients are lying down, 4 electrodes are placed on the wrists and ankles. A little electrical pulse (which is not noticeable) will be send through the body. The impedance analyser calculates the composition of fluid in extracellular, intracellular space, muscle and fat tissue by using the bodie's resistances.

Study burden and risks

1. patients (group 2 and 3) will receive a naso-jejunal tube which is characterized by minimal complications and good patient compliance. Some adverse effects such as nausea, vomiting, diarrhea, cramps and irritation of the nose, throat, are known.

2. The location of the tube will be checked during surgery and there will not be started with feeding untill it is sure that the tube location is correct.
And only when the patient is stable (MAP>60mmHg, gastric retention<100ml/h)

3. 3 times extra blood will be taken in total 15 cc, weight and nutritional status will be measured as described above

4. some time after the end of the study, the investigators can contact the patient , to follow up the longterm outcome

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

Elective surgery
colorectal surgery by cancer
IORT
informed consent

Exclusion criteria

emergency rectal surgery
synchroneous partial liver resection or pulmonary resection
esophageal varices or GI bleeding

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-01-2009
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Bengmark Nasojejunal tube
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-11-2006
Application type:	First submission
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	ID
CCMO	NL13927.060.06