CLIP-trial; CLoser Look Into Postoperative ileus

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- better understanding of postoperative ileus pathofysiology. Besides it become possible to estimate the severity of ileus, and development of ileus by clinical and biochemical parameters.- achieve a database like a control group for future studies...

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

Summary

ID

NL-OMON38965

Source
ToetsingOnline

Brief title
CLIP-trial

Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym
lack of peristalsis postoperative, postoperative ileus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Stichting Coolsingel Rotterdam

Intervention

Keyword: colorectal surgery, observational, postoperative ileus

Outcome measures

Primary outcome

- IL-6 concentration first day postoperative

Secondary outcome

- Opioid consumption postoperatively

- Patient hospitalization length

- First bowel sounds post operation

- Blood test of inflammatory indicator: white blood cell number, neutrophil

percentage, CRP, TNF, IL-6

- Complications (mortality, morbidity)

Study description

Background summary

Postoperative ileus (POI) is a common complication after abdominal surgery. It is a transit cessation of bowel mobility after surgery and presents as an inability to tolerate enteral nutrition, associated with nausea, abdominal distension, and lack of flatus and defecation. Although bowel function literally recovers within 3 to 5 days after operation, in more than 50% cases however, it is not fully recovered 4 days post operation. Delayed recovery of bowel function leads to other serious outcomes such as longer hospitalization, hospital-acquired infections and pulmonary compromise, and of course results in a large increase of medical cost as well.

Opening of the peritoneal cavity and manipulation of the peritoneum and bowel are the main causes of POI. Open procedures significantly delay the recovery of POI. Other factors such as previous surgery, general anaesthesia and postoperative opioid consumption also contribute to the prolonged lack of bowel motility.

Abdominal surgery triggers two different phases: an early neurogenic phase and a late inflammatory response, the latter of which is considered to be a clinically more relevant inhibition of gastrointestinal motility. Pathogenenis of POI have been associated with many clinical conditions, they all contribute to gasto-intestinal (GI) dysmobility through two common pathways. Firstly the inhibitory neural reflexes that increase inhibitory sympathetic activity in the GI tract. Secondly the inflammatory response to intestinal manipulation and trauma. Local macrophages, activated by intestinal manipulation, produce an inflammatory response that results in muscle dysfunction. Especially because of neutrophil infiltration into the intestinal muscularis. Mast cells play also a role according to the study from De Jonge et al A number of studies concentrate on the physical, pharmacological, electrical stimulations of the vagus nerve in order to attenuate POI.

To get a better understanding of the neurolhumoral respons and the effect on gastrointestinal motility there are several studies which take a close look to electrogastrography and different inflammatory markers; interleukine (IL)-1, IL-6, procalcitonine and CRP. Especially IL-1 and -6 seems to play an important role in the pathogenesis of postoperative ileus. Even little manipulation of the bowel induce activity of IL-1 and -6. This results in activation of nitricoxide and prostaglandine, which will cause leucocytes in the circular muscle of the bowel.

However, no data is available till now to answer if these parameter can be used to predict or early diagnose POI. In this study we therefore will investigate the normal values of the different inflammatory parameters after colorectal operation, and set up the database of these parameters in patient with standard medical interventions. The aim if this study is to investigate the feasibility of using inflammatory parameters to predict POI. In addition, this will bring a control group for studies in the future. This can help to interpretate the effects of profylactive therapies objectively in the future.

Study objective

- better understanding of postoperative ileus pathofysiology. Besides it become possible to estimate the severity of ileus, and development of ileus by clinical and biochemical parameters.

- achieve a database like a control group for future studies that will use interventions to treat or prevent ileus

Study design

Prospective case control pilot study

Study burden and risks

There is no serious extra risk or benefit associated with participation in this trial. We will only one time extra blood from the patient by vena punction.

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 who need to undergo elective colorectal surgery ; left or right hemicolectomy, low anterior resection, abdomino perineal resection/ rectumamputation
- age > 18 yr
- signed informed consent

Exclusion criteria

-age younger than 18 years

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	19-08-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43053.078.13