Colonic motility after colonsurgery with diverting stoma; observational study

Published: 13-12-2011
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Purpose:We like to determine the movement of the intestinal contents to measure the peristaltic movement/ motility.

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

Summary

ID

NL-OMON36383

Source
ToetsingOnline

Brief title
CMC-trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
n.v.t.

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: waarschijnlijk Amphia academie of Maatschap Heelkunde Amphia

Intervention

Keyword: colon surgery, motility

Outcome measures

Primary outcome

- migration of the radio-opaque markers

Secondary outcome

time till first faeces production in stoma or rectal after surgery

Study description

Background summary

Introduction:
After colorectal surgery anastomotic leakage is one of the most important complications. This complication has high impact on morbidity and mortality rate. [1,2] Several studies show that a temporary diverting ileostomy protect the distal anastomosis, especially when anastomosis is nearby the rectum.

One of the arguments for a diverting stomy is to prevent faecal contamination of the anatomosis. However, programmes for enhanced recovery after colorectal surgery abolished mechanical bowel preparation. As a consequence faeces remains in the descending loop that can pass the anastomosis. Interestingly, the incidence rate of anastomotic leakage has not been increased after installation of ERAS- programmes. This is shown both in the Amphia Hospital as in other hospitals. [3,4]

It suggests another cause for the protective role of the ileostomy than preventing fecal contamination. We suggest an alternative possibility, that the stomy prevents continuation of the peristaltic wave along the gut and in this way reduces the intracolonic pressure on the anastomosis.

Study objective

Purpose:
We like to determine the movement of the intestinal contents to measure the peristaltic movement/ motility.

Study design

Observational study

Study burden and risks

The risk and extend of burden for the patient is minimal. Radiation pollution will be in total two x-rays of the abdomen, this will be in total 0.3 mSievert per x-ray.
The colonic transit time will be determined with one capsule which contain twelve radiopaque rings, so-called Sitzmarker. This capsule dissolves very easy in the gastro-intestinal tract. When the capsule dissolves, the twelve rings will pursue their way through the colon or remain in position in cases without no or less motility.

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:
low anterior resection with ileostomy
right hemicolectomie
ileostomy closure

Exclusion criteria

immunocompromised
weak pre- operative condition
neo adjuvant chemo radiationtherapy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Radiopaque marker
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-12-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL34570.008.11