The effect of pneumoperiteum during laparoscopic surgery on the paediatric intestine

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON36223

Source
ToetsingOnline

Brief title
Pneumoperitoneum on paediatric intestine

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
minimal invasive surgery, pneumoperitoneum

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: iFABP, intestinal damage, pneumoperitoneum

Outcome measures

Primary outcome

Peroperative measurements of:

• Urinary iFABP: as a measurement of the ischemia in the intestines (Detection limit 40pg/ml pg/ml). Urinary samples are taken each 10 minutes during the pneumoperitoneum, because of the half time of 11 minutes for iFABP. A control sample is taken before the start of the pneumoperitoneum and the last sample is taken 10 minutes after surgery.

• Urinary Creatinin: to calculate iFABP/ creatinin ratio (cut off point 2.2 pg/nmol). In the same samples as iFABP

• Intra-abdominal pressure and insufflation flow on monitor are registered in the same 10 minutes interval as the urine samples

Secondary outcome

Post-operative measurement of:

• Urinary iFABP: Urinary samples by active urination of the patient, after the removal of the urinary catheter (the time is noted), until 24h after the surgery.

• Urinary Creatinin: In the same samples as iFABP

• Restoration of Gastro-intestinal function (per 6h in the first 24h; daily in the first week) (First defecation, first oral feeding, and full oral feeding)

• Hospital stay in days

Study description

Background summary

During laparoscopic surgery there is a pneumoperitoneum created with carbon dioxide to create a working space in the abdomen to visualize the target organs and a proper operating field. An intra-abdominal pressure lower than 14 mmHg is considered safe in a healthy adult patient, however, this in children lower pressures are preferred, but there is no limit objectified in which complications are more prone to occur.
The complications that can occur because of the pneumoperitoneum are based on the physiological changes resulting from the increased abdominal pressure and the carbon dioxide used to create the pneumoperitoneum. Low mesenteric blood supply (due to high abdominal pressure) leads to intestinal injury and the excretion of iFABP in the circulation. This substance will be excreted in the urine, and the intestinal damage can be detected in the urine.
in this study the effect of the pneumoperitoneum on the paediatric intestine will be objectified, in which urinary iFABP will serve as an indicator for intestinal damage.

Study objective

In this study the effect of the pneumoperitoneum on the intestine of children is objectified by measuring the iFABP levels in the urine, as an indicator for the ischemia or damage to the intestine. To exclude any iFABP increase due to intestinal damage of the surgical procedure (by manipulation and resection) we chose to research these levels in children during a laparoscopic Nissen fundoplication.

Primary Objective:
• Is there an effect of the pneumoperitoneum during laparoscopic procedures in the paediatric intestine, by elevation in urinary iFABP concentration and urinary iFABP/creatine ratio?
Secondary Objectives:
• Is there a relation between perioperative urinary iFABP concentration and postoperative gastro-intestinal functions, measured by enteral feeding postoperative?
• Is there a relation between perioperative urinary iFABP/creatine ratio and postoperative gastro-intestinal functions, measured by enteral feeding postoperative?
• Is there a relation between perioperative urinary iFABP concentration and postoperative gastro-intestinal functions, measured by defecation habits postoperative?
• Is there a relation between perioperative urinary iFABP/creatine ratio and postoperative gastro-intestinal functions, measured by defecation habits

postoperative?

Study design

This is an observational prospective cohort study.
The urinary catheter is placed when the patient, and a control sample from the urine is taken before the surgery. After the pneumoperitoneum is completed there will be a sample taken every 10 minutes. The last sample during the surgery is taken 10 minutes after the desufflation of the pneumoperitoneum. The urinary bladder catheter is removed after the last sample, when the patient is still under anaesthesia.
The other control measurements, such as intra-abdominal pressure, blood pressure and urinary output are taken at the same interval points, during the surgery. Postoperative gastro-intestinal measurements are documented at the ward, and when the patient is released home, they will document this with their parents on the questionnaire, for one week postoperative. Any complications after the surgery will be documented for this research.

Study burden and risks

The patients will all receive a bladder catheter (CAD) just before the surgery (when they are under anaesthesia), therefore, there will be no pain of introducing the catheter. The CAD will stay in situ during the surgery and will be removed before the patient is awake. The urinary samples can be drawn from the CAD, which will cause no extra handling of the patient. The risks on complications from a CAD (urinary track infection and false route) are low.
During regular elective laparoscopic Nissen fundoplication there is no specific need for a CAD, however, the anaesthesiologist often requests this to have a proper haemodynamic evaluation during the surgery. The insertion of a CAD before the introduction of the trocars ensures the bladder to be empty, and therefore, a safer introduction of the first subumbilical trocar.
The patients/ parents should also fill out a short questionnaire during one week postoperative, on the enteral feeding and defecation of the patient.
By measuring the iFABP levels during the surgery in upper abdominal surgery (in which the intestines are not manipulated) a clear effect of the pneumoperitoneum on the paediatric intestine is visualized. This is useful for the further use of the pneumoperitoneum and perhaps adaptation of the insufflation pressures during the laparoscopic procedures in children.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age <16 years
Elective laparoscopic Nissen fundoplication

Exclusion criteria

Diagnosis of necrotizing enterocolitis, because of prior elevated iFABP
Emergency surgery
Inflammatory bowel disease, or other bowel disorders, which can cause iFABP elevations.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-05-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL35743.068.11