The loss of gut wall integrity through non-abdominal surgical trauma in adults, children and neonates

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To examine the effect of surgical trauma on mucosal perfusion, intestinal epithelial damage, the inflammatory response and potentially sepsis, following surgery remote to the abdomen in adults, children and neonates,

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON30582

Source
ToetsingOnline

Brief title
Gut damage and inflammation in major non- abdominal surgery

Condition

- Gastrointestinal inflammatory conditions
- Nervous system, skull and spine therapeutic procedures

Synonym
complications after major surgery, inflammtion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: etiology, inflammation, intestinal epithelial damage, major surgery

Outcome measures

Primary outcome

As first outcome measurement, this study will evaluate the origin of intestinal epithelial cell damage, mucosal hypoperfsuion, inflammation, bacterial translocation and postoperative complications. Complications will be defined as the presence of SIRS, sepsis, or evidence of organ failure based on internationally accepted biochemical and/or clinical criteria. We will correlate the increase of studied plasma and urinary markers for intestinal epithelial cell damage and inflammation with the occurence of post-operative morbidity and complications.

The peak levels of studied markers will be correlated with the amount of hypoperfusion, measured by gastric tonometry. The release of intestinal cell damage and inflammation markers will be correlated with the amount of blood loss, duration and extension of surgery.

Secondary outcome

Secondary outcome measurements will consist of duration of intensive care unit stay, postoperative onset of feeding, use of antibiotics.

Study description

Background summary

Children undergoing major surgery often develop systemic inflammatory response syndrome (SIRS) and sepsis. Patients with SIRS and sepsis have an increased

risk of developing multiple organ failure (MOF), which is the leading cause of death in surgical patients.
We hypothesize that surgical stress, such as blood loss causing splanchnic hypoperfusion, in combination with the inflammation caused by significant tissue trauma, leads to intestinal epithelial damage. Subsequently, the loss of normal intestinal barrier function leads to translocation of bacteria causing SIRS and possibly sepsis.
Because newborns, children and adults have a different bacterial colonization of the intestinal tract and the immune system matures only during childhood, we hypothesize to find different intestinal and inflammatory responses during and after surgery in these age groups. Therfore, the study evaluates whether there is any difference in gut damage and inflammatory response between adult, pediatric and neonatal surgical populations.

Study objective

To examine the effect of surgical trauma on mucosal perfusion, intestinal epithelial damage, the inflammatory response and potentially sepsis, following surgery remote to the abdomen in adults, children and neonates,

Study design

The study will be a longitudinal, observational study of adults, children and neonates undergoing major non-abdominal surgery. In adults and children we will study patients that undergo scoliosis repair surgery. In neonates we will study patients undergoing thoracotomy. All patients will subsequently be admitted to ICU, PICU or NICU respectively. In neonates we will sample urine. In adults and children we will only sample blood. We will obtain an initial blood or urinary sample upon induction of anesthesia before surgery commences. Subsequent plasma respectively urine sampling will occur every two hours after the start of surgery, 2 hours after wound closure, and then daily for at least 48 hours. A gastric tonometry catheter will be introduced for measurement of intramucosal CO2 pressure in children and adults.

To study intestinal cell damage we will use I-FABP, ILBP and L-FABP. To study inflammation we will use neutrophil activation product, complement activation and the cytokine response. To study splanchnic hypoperfusion we will perform gastric tonometry.

Study burden and risks

A total of 18 ml and 36 ml of blood will be sampled from respectively children and adults over a time period of 48 hours.
Blood will be sampled from either an arterial or central venous line intra- and immediately post-operatively, and then concurrent with the normal daily blood testing post-operatively.

In neonates we will collect 1 ml urine every 2 hours during surgery and 2, 12, 24 and 48 hours postoperatively. Urine will be sampled from a CAD, which will be placed at any case before start of surgery.
A gastric tonometry catheter will be introduced after aneasthesia for measurement of intramucosal CO2 pressure during surgery in children and adults.
Blood/ urine sampling and gastric tonometry do not bring an extra risk for the patient.

Patients do not directly benefit but all patients that will undergo major surgery in the future will.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children and adults undergoing major spinal surgery and neonates undergoing thoracotomy in the University Hospital Maastricht.
Patients that have an arterial line or central venous access to facilitate plasma sampling.
Patients that have given informed consent

Exclusion criteria

Patients who have any other cause for gut damage, such as inflammation (eg active inflammatory bowel disease), direct surgical trauma (eg abdominal surgery), or artificial circulation (eg cardiopulmonary bypass).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	30-10-2006
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-07-2007
Application type:	Amendment
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	NL12209.068.06