The role of intestinal fatty acid binding protein (iFABP) in the treatment of small bowel obstruction

Published: 29-08-2011
Last updated: 28-04-2024

usefulness of I-FABP in the surgical managment of small bowel obstruction caused by adhesions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON39891

Source
ToetsingOnline

Brief title
I-FABP and small bowel obstruction

Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal therapeutic procedures

Synonym
small bowel obstruction

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Colema BV

Intervention

Keyword: CT-abdomen, I-FABP, small bowel obstruction, surgery

Outcome measures

Primary outcome

I-FABP values in blood and urine, radiological findings, decision for surgery.

Secondary outcome

Spontaneous recovery, therapeutic effect water-soluble contrast

Study description

Background summary

Small bowel obstruction due to adhesions forms a large part of postoperative morbidity in Western countries. In the management of small bowel obstruction it is often said to "never let the sun rise or set on small-bowel obstruction" because they are sometimes fatal if treatment is delayed. This traditional surgical canon is no longer followed, since for a large group of patients it is unclear who can be treated conservatively, and in which cases a surgical intervention is needed. Unnecessary surgical intervention needs to be avoided since this is accompanied with risks of intestinal damage, anastomotic leakage in case of resection and a prolonged postoperative ileus afterwards.
Water-soluble contrast such as gastrograffin may aid in the management of small bowel obstruction due to adhesions as both a diagnostic tool and a therapeutic tool (it is a laxative). Also a CT-scan of the abdomen may help to better differentiate between those patients taht can be treated conservatively and patients that need surgery. Despite these different diagnostic modalities, timing and decision for surgery remains an important clinical problem. A combination of clinical symptoms, experience of the surgeon and radiologic findings ultimately result in the final decision. Patients that require surgery for small bowel obstruction often have a longer period of strangulation of the small bowel leading to intestinal damage. A marker with sufficient sensitivity and specificity for intestinal damage may be of importance in selection of patients with small bowel obstruction for surgery.
Intestinal-Fatty Acid Binding Protein (I-FABP) is a cytosolic protein that resides in the intestinal epithelium and is released in the blood following intestinal damage. In previous experimental and clinical studies has been shown that I-FABP is strongly associated with the intestinal damage and is increased in mesenteric ischemia. We hypothesize that increased levels of I-FABP aid in

the surgical management of small bowel obstruction.

Study objective

usefulness of I-FABP in the surgical managment of small bowel obstruction caused by adhesions.

Study design

Blood and urine will be sampled at time of diagnosis (day 0) untill three days afterwards. I-FABP values will be compard with clinical outcome and radiological findings.

Study burden and risks

Venous puncture will be performed, in total 4 times. This will be in most cases part of regular blood sampling. Collection of urine is without risks.
Benefit: This study will aid in a more adequate surgical management of small bowel obstruction.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Age >18 years
2. diagnosis of small bowel obstruction based on adhesions (at least 1 abdominal surgerical event in the history)
3. signed informed consent

Exclusion criteria

1. patients unfit for surgery
2. Patients that are unable to undergo a CT

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):	27-09-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-03-2014
Application type:	Amendment
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	NL37278.060.11