The role of intestinal fatty acid binding protein (I-FABP) in diagnosing acute mesenteric ischemia

Published: 04-08-2011
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Evaluation of I-FABP as diagnostic tool in mesenteric ischemia.

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

Summary

ID

NL-OMON39607

Source
ToetsingOnline

Brief title
I-FABP in mesenteric ischemia

Condition

- Gastrointestinal conditions NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
bowel ischemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CT-angiography, I-FABP, Mesenteric ischemia

Outcome measures

Primary outcome

Diagnosis, CT-angiography, moment of surgery, I-FABP concentration in blood

and urine samples

Secondary outcome

Mortality, final diagnosis, unnecessary surgery (negative laparotomy/ scopy)

Study description

Background summary

Mesenteric ischemia is a severe disease accompanied with a substantial morbidity and mortality of up to 40%-70%. Early diagnosis is essential to give adequate treatment and to prevent severe and irreversible intestinal damage. However, diagnosis of mesenteric ischemia is challenging, especially in the early stage of the disease due to its aspecific symptoms. Clinical symptoms can vary between vague abdominal complaints to signs of peritonitis caused by transmural ischemia.
The incidence of acute mesenteric ischemia is estimated to be 0,5% of all hospital admissions, with a marignal increase due to the increasing number of elderly patients. An arterial embolus or thrombosis causes mesenteric ischemia in 70-80% of cases. The superior mesenteric artery is occluded in most cases. Laboratory investigation typically shows a leucocytosis and a metabolic acidosis. Markers such as (D)-lactate and D-dimers can also be elevated, however these markers are not specific.
CT-angiography is the gold standard at this moment for diagnosing acute mesenteric ischemia with a good sensitivity and good specificity. However, CT-angiography is accompanied with several disadvantages such as radiation, renal impairment and a potential allergic response to the iv-contrast. Since the clinical symptoms are not always very clear and rapid intervention is of the essence, many patients with a suspicion of mesenteric ischemia are subjected to a CT-angiography, however with a negative outcome. Furthermore, it is unknown whether the high sensitivity and specificity as described in the literature in the expert centres can be extrapolated to daily practice.
Intestinal-Fatty Acid Binding Protein (I-FABP) is a cytosolic protein which is

present in the intestinal epithelial cell. It is clearly elevated in blood and urine samples when intestinal damage occurs. Previous experimental studies have shown that the amount of I-FABP is predictive of mesenteric ischemia and correlates well with the extent of intestinal damage. In this study we investigate whether I-FABP can be used as a diagnostic tool in mesenteric ischemia as compared with the gold standard (CT-angiography).

Study objective

Evaluation of I-FABP as diagnostic tool in mesenteric ischemia.

Study design

Blood and urine samples will be taken from subjects suspected of mesenteric ischemia at the time of diagnosis (day 0) and after 1 and 5 days.
Values of I-FABP in blood and urine will be correlated to results of the CT-angiography and clinical outcome.

Study burden and risks

Venous puncture will be performed (3x). This will mostly be part of the regular blood sampling. Collection of urine is without risks.
Benefit: this study will contribute to a better diagnosis of mesenteric ischemia in the future.

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

Age >18 years
Suspicion of acute mesenteric ischemia
Signed informed consent

Exclusion criteria

Patients that underwent abdominal surgery within 7 days prior to presentation

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):	21-09-2011
Enrollment:	263
Type:	Actual

Ethics review

Approved WMO Date:	04-08-2011
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:	19-01-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2013
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	NL37101.060.11