

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

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	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 marginal 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**

### **Public**

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### **Scientific**

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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

CCMO

### ID

NL37101.060.11