

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON26895

### Source

NTR

### Brief title

FAMOUS

### Health condition

mesenteric ischemia

## Sponsors and support

**Primary sponsor:** Catharina hospital Eindhoven

**Source(s) of monetary or material Support:** self supporting

## Intervention

## Outcome measures

### Primary outcome

I-FABP concentraties in blood and urine compared with result of CT-angiography and surgery.

### Secondary outcome

1. Mortality;
2. Negative laparotomy;
3. Other diagnosis.

## Study description

### Background summary

Mesenteric ischemia is a potentially lethal condition in which early diagnosis is pivotal. Since simple and readily available diagnostic tools are lacking, mesenteric ischemia is still accompanied with a high morbidity and mortality.

CT-angiography is the golden standard to assess acute mesenteric ischemia with a good sensitivity and good specificity. However, a CT-angiography is associated with important disadvantages for the patient and since the early presentation may be atypical, a CT-angiography is often performed at a later stage of the disease. Intestinal-Fatty Acid Binding Protein (I-FABP) is a cytosolic protein that resides in the intestinal epithelial cell and is detectable in urine and blood during intestinal ischemia. In previous experimental and clinical studies has been shown that iFABP values in blood and urine strongly correlate with intestinal damage and ischemia. In this study we will investigate whether iFABP can be used as a primary diagnostic tool to detect and exclude mesenteric ischemia. I-FABP concentrations in plasma will be correlated to the results of CT-angiography and/ or surgery in a multicentre setting.

### Study objective

iFABP can be used as a primary diagnostic tool to detect and exclude mesenteric ischemia.

### Study design

Day of presentation (0);

Day 1;

Day 5.

### Intervention

N/A

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

1. Age  $\geq$  18 jaar;
2. Suspection of acute mesenteric ischemia;
3. Signed informed consent.

### Exclusion criteria

Previous abdominal surgery within 1 week of presentation.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2011

Enrollment: 263

Type: Anticipated

## Ethics review

Positive opinion

Date: 24-08-2011

Application type: First submission

## 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
NTR-new	NL2890
NTR-old	NTR3036
Other	METC Eindhoven : M11-1125
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

1. Oldenburg WA, Lau LL, Rodenberg TJ, Edmonds HJ, Burger CD. Acute mesenteric ischemia: a clinical review. Arch Intern Med 2004;164:1054-62.PMID 15159262.<br>
2. Kassahun WT, Schulz T, Richter O, Hauss J. Unchanged high mortality rates from acute occlusive intestinal ischemia: six year review. Langenbecks Arch Surg 2008;393:163-71.PMID 18172675.<br>
3. Sise MJ. Mesenteric ischemia: the whole spectrum. Scand J Surg;99:106-10.PMID 20679047
4. Thuijls G, van Wijck K, Grootjans J, Derikx JP, van Bijnen AA, Heineman E, Dejong CH, Buurman WA, Poeze M. Early diagnosis of intestinal ischemia using urinary and plasma fatty acid binding proteins. Ann Surg;253:303-8.PMID 21245670.<br>
5. Menke J. Diagnostic accuracy of multidetector CT in acute mesenteric ischemia: systematic review and meta-analysis. Radiology;256:93-101.PMID 20574087.<br>
6. Thuijls G, Derikx JP, van Wijck K, Zimmermann LJ, Degraeuwe PL, Mulder TL, Van der Zee DC, Brouwers HA, Verhoeven BH, van Heurn LW, Kramer BW, Buurman WA, Heineman E. Non-invasive markers for early diagnosis and determination of the severity of necrotizing enterocolitis. Ann Surg;251:1174-80.PMID 20485148.