Potential new markers in the diagnosis of intestinal ischemia

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

Summary

ID

NL-OMON30572

Source
ToetsingOnline

Brief title
New markers for intestinal ischemia

Condition

- Gastrointestinal vascular conditions

Synonym
Intestinal ischemia; Intestinal infarction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diagnosis, Intestinal ischemia, Marker

Outcome measures

Primary outcome

Diagnosis of clinical relevant intestinal ischemia will be assessed by findings during surgery or autopsy or experts.

We will find two groups: 1) patients without clinical relevant intestinal ischemia and 2) patients with intestinal ischemia. A small group of patients will remain in whom diagnosis is not clear. A group of experts will discuss diagnosis.

At the end we will find a rest group with no clear diagnosis. We will report them and calculate a worst-case scenario with these data.

Secondary outcome

None.

Study description

Background summary

Acute intestinal ischemia is potentially a lethal disease with high mortality (60-80%!). This high mortality is caused by late diagnosis due to large diversity of etiology of intestinal ischemia (arterial emboli, arterial thrombosis, aorta dissection, etc) and low specificity and sensitivity of current tests.
Therfore it is important to find useful diagnostic tools for patients who are suspected for intestinal ischemia. Previous results show that Intestinal Fatty Acid Binding Protein (I-FABP) is increased in patients with intestinal ischemia. The clinical usefulness of FABPS in patients suspected for intestinal ischemia is unknow. L-lactate and D-lactate are also potential predictors for intestinal ischemia.

Study objective

First goal is the evaluation of plasma and urinary FABP levels as useful indicators for diagnosis of intestinal ischemia.
Second goal is to study whether combinations of proteins from the family of FABPs provide insight in the localization of intestinal ischemia.
Third goal is the assessment of L-lactate and D-lactate as useful markers for diagnosis of intestinal ischemia.

Study design

All patients with suspicion for intestinal ischemia based on signs and symptoms will be asked to participate in this prospective pilot-study. After informed consent 5 ml blood and urine will be sampled as soon as possible and 4 hours later.

Study burden and risks

Two times 5 ml blood will be sampled. At these time points we will ask the patients to collect urine. This is no extra burden or risk for the patients.

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

Patients admitted to AZM who are suspected for intestinal ischemia.

Exclusion criteria

None.

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):	01-09-2007
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2007
Application type:	First submission

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	NL15694.068.06