Early markers of gastrointestinal ischemia

Published: 07-05-2008
Last updated: 07-05-2024

To evaluate the use of the early serum markers I-FABP, D-dimer, DAO and alpha-GSTin predicting CGI one by one.To evaluate the use of Citrulline to determine the bowel function in patients with CGI.

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

Summary

ID

NL-OMON32084

Source
ToetsingOnline

Brief title
Early markers of gastrointestinal ischemia

Condition

- Gastrointestinal vascular conditions

Synonym
gastrointestinal ischemia, impairment of circulation of the gastrointestinal tract

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: early, gastrointestinal, ischemia, marker

Outcome measures

Primary outcome

Test results serological markers

Secondary outcome

Data that will be recorded are:

§ Pathology on referral

§ Demographic data:

o Age

o Gender

o Ethnicity

o Body length and weight

§ Physical examination

§ Cardiovascular risk factors

§ Alcohol and tobacco use

§ Medication use

§ Medical history

§ Family history

§ Test results sugar absorption test

Study description

Background summary

Diagnosing chronic gastrointestinal ischemia (CGI) is a challenging problem. There is no single, simple test with a high sensitivity available to detect this condition. Presenting symptoms of CGI are postprandial pain, which may lead to weight loss typically caused by fear of eating, exercise related pain and diarrhoea. At the moment, patients referred for evaluation of possible CGI are evaluated using computed tomography angiography (CTA) and 24 hour gastric and jejunal tonometry (24hrTM). Patients with abdominal arterial stenosis on CTA and abnormal 24hrTM (i.e. GI ischemia) are advised to undergo treatment. CTA is a minimally invasive technique to detect and define abdominal artery stenoses, while 24hrTM measures ischemia defined as insufficient oxygen delivery and/or consumption of the metabolic demands. However, 24hrTM is an invasive and cumbersome procedure to perform. Serum markers for CGI would be of great value in diagnosing these patients and contribute to the diagnostic properties as a single, non-invasive test method.
This study is performed to further establish the potential role of serum ischemia markers in patients analyzed for possible CGI. Several early serum markers will be tested and compared to the results of a functional test for CGI (24hrTM) and visualization of the abdominal arteries (CTA).

Study objective

To evaluate the use of the early serum markers I-FABP, D-dimer, DAO and alpha-GST
in predicting CGI one by one.
To evaluate the use of Citrulline to determine the bowel function in patients with CGI.

Study design

A prospective patient-control pilot study conducted by the Department of Gastroenterology & Hepatology, Erasmus MC University Medical Center Rotterdam.

Study burden and risks

Patients will be evaluated according to the CGI work-up using CTA and 24hrTM. During 24hrTM patients receive intravenous infusion of omeprazole. From the same catheter, 5 blood samples will be drawn (total 165 ml). A non-invasive sugar absorption test in urine will be performed during this admission, which will not be prolonged by participating in this study.

Healthy volunteers:
1. Physical examination, cardiovascular risk factors
2. A non-invasive duplex ultrasound will be performed after 6 hours fasting.
3. Subsequently, after insertion of an intravenous catheter with minimal risks, a blood sample will be drawn at baseline, 30 minutes, 1, 2 and 4 hr after a standard liquid compound meal (total 165 ml).

All volunteers will be offered expense allowance and receive ¤ 50,- for participating in the study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
3015 CE Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>18 years old

Exclusion criteria

Use of NSAID*s, ascal, acetylsalicylic acid, acenocoumarol

Pregnant or lactating women

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2008
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	07-05-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL22082.078.08