Mucosal saturation measurements in patients suspected for chronic gastrointestinal ischemia

Published: 09-11-2007
Last updated: 10-05-2024

Evaluation of the diagnostic value of stomach and small bowel mucosal oxygen saturation measurements in patients suspected for chronic gastrointestinal ischemia.Determination of normal mucosal oxygen saturation values in patients without chronic...

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

Summary

ID

NL-OMON31714

Source
ToetsingOnline

Brief title
Musosal saturation in chronic GI ischemia

Condition

- Gastrointestinal vascular conditions

Synonym
chronic gastrointestinal ischemia

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: bloodflow, chronic gastrointestinal ischemia, diagnosis, mucosal oxygen saturation

Outcome measures

Primary outcome

Diagnostic value of mucosal saturation measurements in patients with chronic

gastrointestinal ischemia.

Secondary outcome

Normal mucosal oxygen saturation values in patients without chronic

gastrointestinal ischemia or a gastrointestinal vascular stenosis.

Changes in mucosal saturation measurements in patients treated for chronic

gastrointestinal ischemia.

Study description

Background summary

The diagnosis chronic gastrointestinal ischemia (CGI) is often made a late phase of the disease. This is explained by the fact that it is relatively rare disease (in the Netherlands 50 - 150 patients / year), also diagnostics to evaluate patients with possible CGI are cumbersome, special equipment is required and some experience is necessary. The past decade, gastrointestinal tonometry has proved to be of major importance in the diagnosis of CGI. The principle of tonometry is the measurement of intraluminal CO2, which is elevated in patients with CGI. Combined with anatomical investigation (CT- or MR-angiography) the diagnosis CGI can be made with an acceptable sensitivity and specificity. The major disadvantage of tonometry are invasive (2 catheters have to be placed in stomach and jejunum) and longer durations (upto 24 hours). Furthermore, is tonometry cumbersome: some experience with the technique is necessary. The tonometry technique is relatively unknown, also it does not resemble any technique currently used in the field of gastroenterology. This, and the forementioned disadvantages, make that tonometry is still not accepted as a common diagnostic technique and is only used in a few clinics for this purpose.

Recently, a new endoscopic technique for measurement of mucosal oxygen saturation has become available. This mucosal saturation of stomach and small bowel mucosa seems directly related to the overall bloodflow in these organs. In a recent article this technique proves of value in a small number of patients with CGI.

Study objective

Evaluation of the diagnostic value of stomach and small bowel mucosal oxygen saturation measurements in patients suspected for chronic gastrointestinal ischemia.
Determination of normal mucosal oxygen saturation values in patients without chronic gastrointestinal ischemia or a gastrointestinal vascular stenosis.

Study design

Prospective; comparison of results of mucosal saturation measurements with the results of the standard work-up (tonometry, CT/MR-angiography and consensus diagnosis of the workinggroup on chronic gastrointestinal ischemia).

Study burden and risks

1) the duration of the gastroduodenoscopy will be a few minutes longer; the overall risk of the measurements is very low (almost zero).
2) patients having a control gastroduodenoscopy after treatment:
- burden: repeated gastroduodenoscopy
- risks: comparable to the overall risk of a diagnostic gastroduodenscopy (very low; 1 : 3000).

Duplex ultrasound in patients without chronic gastrointestinal ischemia or a gastrointestinal vascular stenosis is a non-invasive procedure without risks.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

s Gravendijkwal 230
3015 CD Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

s Gravendijkwal 230

3015 CD Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- > 18 and < 80 yrs of age
- capable of giving informed consent

Exclusion criteria

- not capable to undergo gastroduodenoscopy
- to determine normal values: gastrointestinal vascular stenosis

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):	15-11-2007
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-10-2008
Application type:	Amendment
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	NL19147.078.07