Validation of a new PCO2 measurement catheter

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Primary Objective: for each new catheter design: in-vitro establishment of time-dependent correction factors for saline-use and establish the accuracy of CO2 measurement with the capnograph. In-vivo: establish the feasibility and measurement errors...

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

Summary

ID

NL-OMON34918

Source
ToetsingOnline

Brief title
new CO2 catheter

Condition

- Gastrointestinal vascular conditions

Synonym
splanchnic ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: via de eigen middelen van de maatschap

Intervention

Keyword: catheter, gastric, PCO2

Outcome measures

Primary outcome

Air tonometry: a. precision and bias of PCO2 measurement

Fluid tonometry: a. correction factors for 10, 20, and 30 minutes

equilibration time, b. precision and bias calculation for each dwell time

Patient study: measurement errors with use of the tonocap in patients

Secondary outcome

1.Blood gas analyser: correction factor for PCO2 measurement from saline.

2.Patient study:

a.The handling characteristics for placement in the small bowel

b.time needed for small bowel placement during fluoroscopy

c.handling characteristics during 24 hour measurement

d.patient (in)convenience during 24 hour measurement

Study description

Background summary

Gastrointestinal ischemia is a notoriously difficult diagnosis. Both diagnostics on vessel anatomy and a functional test to show ischemia in the GI tract are necessary. Currently only gastrointestinal PCO2 tonometry has been validated as accurate measure of gastric ansd small bowel ischemia. In this test a balloon-tipped catheteris placed via te nasal route in tghe stomach or small bowel. By injection and aspiration of fluid or air the luminal PCO2 can be measured. With air measurement the catheter is connected to a special capnograph, with fluid tonometry, the aspirated fluid is measured in a standard blood gas analyser. Ischemia is characterised by local PCO2 accumulation. Currently, this is the only validated test for detection of GI ischemia.

However, bnecause the test is both time-consuming and relatively complicated it used (too) infrequently.
In Enschede we have experience in > 1000 patients with this test. The diagnostic accuracy is high, and studies with sufficient follow-up have shown its clinical relevance for patient selection for surgery, urgency for vascular procedures and follow-up. Altough there is increasing research to alternative functioanl test, all currently available alternatives are either unvalidated or less accurate.
Because the current firm that markets the catheters and capnographs has stopped production we were urgently llooking for an alternative because stopping these measurements would severely limit our clinical decision making process.
We have therefore contacted the firm that has produced these catheters for the last decade for a solution. They agreed to resume production, with the intent to get CE certification, and then market the catheter. The current study has therefore two goals: 1) to establish data needed for a CE registration and 2) to be able to continue this invaluable diagnostic tool in patients suspected for GI-ischemia.

Study objective

Primary Objective: for each new catheter design: in-vitro establishment of time-dependent correction factors for saline-use and establish the accuracy of CO2 measurement with the capnograph. In-vivo: establish the feasibility and measurement errors in subjects analysed for GI-ischemia detection.
Secondary Objective(s): (1) ease-of-use of the catheters (time needed for small bowel placement), handling characteristics and patient (in)convenience during 24 hour measurement. Areas for improvement for catheter design.

Study design

observational study

Study burden and risks

not applicable: the standard work-up will be performed, only the catheter will differ

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

patienst referred for potential gastrointestinal ischemia (postprandial pain, weight loss or diarrhea, otherwise unexplained, or associated with vascular stenoses)

Exclusion criteria

Age < 18 years,
Poor clinical condition which would make the diagnosis of GI ischemia clinically unimportant.
End-stage liver disease
End-stage cardiopulmonary disease.
Hemorrhagic disorders
Severe esophageal inflammation

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):	15-07-2010
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	nasogastric or nasojejunal balloon-catheter for sampling of air or fluid via a closed circuit
Registration:	No

Ethics review

Approved WMO

Date:	22-06-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL31471.044.10