Endoscopic Measurements of Mitochondrial Oxygen Tension: a pilot study

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To determine the feasibility of the MitoPO2 measurements during upper endoscopy.

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

Summary

ID

NL-OMON42975

Source
ToetsingOnline

Brief title
Endo-mitoPO2-study

Condition

- Gastrointestinal vascular conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
chronic gastro-intestinal ischemia, lack of oxygen of the intestine

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: chronic gastro-intestinal ischemia, mitochondrial oxygen tension, upper endoscopy, visible light spectroscopy

Outcome measures

Primary outcome

To determine the feasibility of the MitoPO2 measurements during upper

endoscopy.

Secondary outcome

To compare MitoPO2 measurements with VLS measurements.

Study description

Background summary

Adequate oxygen supply to the tissues is a required condition for human life, moreover for life of all mammalians. Adequate and reliable measurements of tissue oxygenation are important for diagnosis and treatment decisions in a broad spectrum of diseases. Many techniques have been developed for oxygen measurements in vivo but the ultimate goal is to measure oxygen at the lowest level, at the mitochondria. Mik et al. introduced the protoporphyrin IX-triplet state lifetime technique (PpIX-TSLT) for measuring PO2 in mitochondria (mitoPO2). The technique resulted in the development of the COMET monitor, a clinical monitor for assessment of Cellular Oxygen METabolism, allows cutaneous mitoPO2 measurements to be made in humans5. This non-invasive technique is not yet tested in the stomach and small intestine during upper endoscopy. If it is possible to measure mitoPO2 in the gastrointestinal tract, many purposes are supposable. For example, mitoPO2 measurements can be used in the work-up of chronic gastrointestinal ischemia (CGI). CGI is the result of insufficient blood supply to the gastrointestinal tract. Patients with chronic gastrointestinal ischemia (CGI) suffer from severe postprandial abdominal pain and weight loss, usually caused by atherosclerotic stenosis of the supplying gastrointestinal arteries. The diagnosis of CGI remains challenging as chronic abdominal pain due to other causes is common and stenosis of the mesenteric arteries are often asymptomatic due to extensive collateral circulation. The standard diagnostic work up includes assessment of clinical symptoms, radiological imaging and a functional test as visible light spectroscopy (VLS) or tonometry resulting in an expired-based consensus diagnosis. Current

diagnostic work-up is extensive with various investigations in the absence of just one specific test to diagnose CGI. Hence, a reliable, non-invasive test is needed to assess the oxygenation of the gastrointestinal tract.

Study objective

To determine the feasibility of the MitoPO2 measurements during upper endoscopy.

Study design

Inclusion
Healthy volunteers with no gastrointestinal complaints and unremarkable medical history will be asked to participate in our study through information folders in the Erasmus MC, Rotterdam. This folder will provide information about the study and the study procedure, and also how to contact the research investigator. If people are interested, they can contact the coordinating investigator for a consult to obtain further information. They will receive the patient information folder. If a healthy volunteer decides to participate in the study, he or she will sign the Informed Consent Form and the abdominal duplex ultrasound to determine patent gastrointestinal arteries and the upper endoscopy will be scheduled.

Intervention
The healthy volunteers will drink 5-aminolevulinic acid (ALA, Gliolan 30 mg/ml) 4 hours before the upper endoscopy. The dose of Gliolan will be 20 mg/kg weight. Four hours after the administration of Gliolan the upper endoscopy will be performed.
Healthy volunteers can choose if they want sedation or not during the endoscopy. Sedation will be 2.5-5 mg midazolam combined with 0.05 mg fentanyl intravenously prior to the endoscopy. The MitoPO2 measurements will be performed with the COMET measurement system during upper endoscopy using a sterile single use fiberoptic-catheter (MUCS000001, LightGuideOptics, Germany),that can be passed through the accessory channel of the endoscope. Measurements of the MitoPO2 will be performed at three sites in the stomach and duodenum: antrum of the stomach, descending duodenum and duodenal bulb. Three repeated readings will be taken at different areas of each location. The average of the three readings per location will be regarded as the actual measurement of that specific location. After three MitoPO2 measurements at a location, also three VLS measurements will be performed at that specific location. A fiberoptic catheter-based oximeter (T-Stat 303 Microvascular Oximeter, Spectros, Portola Valley, California, USA) will be passed through the accessory channel of the endoscope. To prevent luminal spasms butylscopalamin 20mg is admitted intravenously before the start of VLS measurements.

Afterwards, healthy volunteers with sedation will be brought to the endoscopy

recovery room to sleep off. If no sedation is used, healthy volunteers are required to go immediately after the endoscopy. It is important to notice that they should avoid exposure to strong light sources (eg. direct sunlight or brightly focused indoor light) of eyes and skin for 24 hours after administration of Gliolan. The total duration of the upper endoscopy will be 15-20 minutes.

Follow-up
There is no follow-up of the healthy volunteers in this study. Obviously, if during upper endoscopy findings are detected, the healthy volunteer will be referred to our outpatient clinic for further analysis and treatment.

Study burden and risks

- risk of upper endoscopy without invasive intervention is very low, especially when no sedation is used
- Visible Light Spectroscopy measurements are safe and non-invasive
- mitochondrial oxygen tension measurements are safe and non-invasive
- intake of Gliolan (ALA) causes photosensitivity, but when the participant avoids exposure to strong light sources, there is no risk

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

- * 18 years
- Informed consent
- Unremarkable medical history (no gastroenterologic diseases or surgery, no cardiac or pulmonal diseases)
- No gastrointestinal complaints
- Patent gastrointestinal arteries determined by abdominal echo duplex

Exclusion criteria

- < 18 years
- unable to give informed consent
- Pregnancy
- Acute or chronic porphyria
- Hypersensitivity for ALA or porphyrin
- Significant stenosis of celiac artery and/or superior mesenteric artery by abdominal echo duplex
- Renal impairment
- Liver impairment

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):	29-03-2017
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO Date:	08-12-2016
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	NL59177.078.16