Magnetic Resonance flow measurements of mesenteric arteries and veins and portal vein with food stimulation and mitochondrial oxygen measurements during routine upper endoscopy in patients suspected of chronic gastro-intestinal ischemia

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To determine the difference in baseline MR flow measurements and post-prandial MR flow measurements between patients diagnosed with CGI and patients not diagnosed with CGI. To gather information on the potential of endoscopic mitochondrial oxygen…

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

Summary

ID

NL-OMON55671

Source
ToetsingOnline

Brief title
MR flow MitoO2 study

Condition

- Gastrointestinal vascular conditions

Synonym
chronic gastro-intestinal ischemia; oxygen deficiency of the gastro-intestinal 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: chronic gastro-intestinal ischemia, Flow measurements, food stimulation, MRI

Outcome measures

Primary outcome

- To determine the difference in baseline MR flow measurements and post prandial MR flow measurements between patients diagnosed with CGI and patients not diagnosed with CGI

- To gather information on the potential of endoscopic mitochondrial oxygen measurements in diagnosing CGI in patients suspected of CGI.

Secondary outcome

- To determine which vessel or which combination of vessels best differentiates between patients diagnosed with CGI and patients not diagnosed with CGI by MR flow measurement

- The severity of abdominal pain in course of time after stimulation with nutritional drink, using the Numeric Pain Intensity scale at baseline and 20, 30 and 40 minutes after nutritional drink.

- To determine the difference in MR flow measurements of the mesenteric vessels prior to and after treatment in patients diagnosed with CGI with persistent relief of symptoms after treatment.

Study description

Background summary

The diagnosis of chronic gastro-intestinal ischemia (CGI) remains a clinical challenge because this diagnosis is difficult to distinguish by the frequent incidence of chronic abdominal pain and asymptomatic stenosis of the mesenteric arteries1.
The standard diagnostic work up includes medical history, anamnesis and physical examination, radiological imaging and a functional test as visible light spectroscopy (VLS)2-4 or tonometry5-7. A multidisciplinary team consisting of a gastroenterologist, a vascular surgeon and an interventional radiologist, all specialized in CGI, discusses all patients which results in an expert based consensus diagnosis. Currently, there is no specific test to diagnose CGI.
In literature, Magnetic Resonance (MR) techniques are described by which the flow in the mesenteric vessels is measured pre- and post-prandial in healthy volunteers and CGI patients8-12. The flow in the mesenteric vessels increases postprandial (hyperemia). However, this increase in post-prandial flow compared to pre-prandial appeared less in CGI patients compared to the healthy volunteers. In some CGI patients, even a decrease of the post-prandial compared to pre-prandial flow was seen.
We might be able to distinguish patients with CGI from patients without CGI with MR flow measurements with food stimulation.
As mentioned it is standard practice to perform a functional test such as VLS and tonometry, but both have limitations. An easy-to-use and accurate functional test to diagnose CGI is highly desired. Protoporphyrin IX-triplet state lifetime technique (PpIX-TSLT) is a novel method used to measure oxygen in mitochondria13. After administration of 5-aminolevulinicacid (ALA) mitochondrial PpIX increases. Green light is used to excite PpIX during the measurements, inducing light emission. After collision with oxygen molecules PpIX returns to its ground state, ceasing light emission. The duration of light emission is measured. When few mitochondrial oxygen is present, collisions are less likely to occur resulting in a longer duration of light emission. A previous study has proven feasibility of endoscopic mitochondrial oxygen measurements in volunteers. Yet no information on the potential of endoscopic mitochondrial oxygen measurements in diagnosing CGI in patients suspected of CGI is available.

Study objective

To determine the difference in baseline MR flow measurements and post-prandial MR flow measurements between patients diagnosed with CGI and patients not diagnosed with CGI. To gather information on the potential of endoscopic mitochondrial oxygen measurements in diagnosing CGI in patients suspected of

CGI.

Study design

Prospective cohort study.

Study burden and risks

The MR flow measurements will take 1 hour to 1.5 hour during one additional visit besides the standard work-up for CGI patients. No contrast agent or radiation is used for the MR flow measurements. Because most patients with CGI present with post-prandial pain, abdominal pain may occur when stimulation with the nutritional drink starts. We will be aware of this pain and ask the patient several times if the pain occurs and stop if necessary.
The risks of mitochondrial oxygen measurements during routine upper endoscopy are very low, especially when no sedation is used. Oral administration of Gliolan (for PpIX induction) has a good safety profile. The risk of mucosal phototoxicity during upper endoscopy is considered low, since the COMET uses short-pulsed excitation and very low total light dosage. To limit the potential effects of phototoxicity, patients will be instructed to avoid exposure to direct sunlight of eyes and skin for 24 hours after administration of Gliolan.

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

1. Patients suspected of CGI referred to our hospital for further analysis
2. Age >= 18 years
3. Patients who gave informed consent

Exclusion criteria

1. Age < 18 years
2. Unable to give informed consent
3. Pregnancy
4. Contra-indications for MRI:
a. Metal implants which cannot be removed. E.g. cardiac pacemakers/ICD, aneurysm clips, metal stents, artificial heart valve, cochlea/retinal implants, hearing aids, dentures with magnetic click system or with other metal accessories, tattoos with metallic dye, metal plates/pins/screws of bones, piercings
b. Claustrophobia
c. Inability to lie still for 1 hour to 1,5 hours
5. Other criteria the physician considers are not compatible with this study
6. Contra-indications for MitoO2 measurements:
a. Acute or chronic porphyria
b. Hypersensitivity for ALA or porphyrin
c. Alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), or bilirubin of >2 times upper limit of normal

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-02-2017
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-08-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-07-2021
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
ClinicalTrials.gov	NCT02875600
CCMO	NL54995.078.15