PRomoting early diagnosis Of chronic Mesenteric ISchEmia by a mesenteric artery calcium score based risk stratification and detection of postprandial mucosal ischemia by butyrate breath testing

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Facilitating diagnosis of chronic mesenteric ischemia (CMI) using 1) the mesenteric artery calcium score (MACS) and 2) mucosal ischemia detection by butyrate breath testing

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

Summary

ID

NL-OMON53338

Source
ToetsingOnline

Brief title
PROMISE study

Condition

- Gastrointestinal vascular conditions

Synonym
Chronic mesenteric ischemia, intestinal oxygen shortage

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,Maag Lever Darm Stichting

Intervention

Keyword: 13C-butyrate, breath test, calcium scores, mesenteric ischemia

Outcome measures

Primary outcome

1) MACS: An existing abdominal CT is used to calculate the MACS of the celiac artery and superior mesenteric artery.

2) Butyrate breath testing: Patients will receive 13C-butyrate dissolved in a high caloric drink (Nutridrink). Multiple test tubes filled with expired air of 13CO2 will be collected during a period of 2 hours.

Secondary outcome

- To determine cut of values for the MACS with high specificity and high negative predictive value.

- To validate the symptom and CT based MACS score chart for early risk stratification of patients with suspected CMI.

- To investigate how CMI affects the gut microbioma and which specific microbial DNA fragments in blood can indicate ischemic damage to the intestinal tissue measured before and after stentplacement

- To assess if specific DNA fragments in blood, associated with cell death due to ischemia, could serve as potential biomarkers for the severity and presence of CMI

- To investigate the difference of cytokeratin fragments in blood before and

after stent placement, and which fragments can serve as diagnostic markers for

the type and location of cell death in intestinal ischemia?

Study description

Background summary

CMI is an incapacitating disease and timely diagnosis remains problematic. Despite the substantial compensatory capacity of the mesenteric circulation CMI is relatively common, its incidence being comparable to other well-known diseases like Crohn's disease.
Diagnostic tools are needed for two purposes since the exclusion of CMI currently requires a cumbersome complication-prone diagnostic workup and since a definitive diagnosis is mainly established per exclusionem. First, a sensitive test is desirable to rule out CMI and avoid excessive diagnostic investigations. Quantification of mesenteric arterial calcification on computed tomography (CT) seems suitable for this purpose, synonymous with the coronary artery calcium score. Second, a specific test is required confirming CMI by detection of mucosal ischemia during a meal, when oxygen demand peaks. A breath test, based on the requirement of oxygen to absorb and metabolize 13C-butyrate in the enterocyte, could detect mucosal ischemia

Study objective

Facilitating diagnosis of chronic mesenteric ischemia (CMI) using 1) the mesenteric artery calcium score (MACS) and 2) mucosal ischemia detection by butyrate breath testing

Study design

Multicentre prospective cohort studies.

Study burden and risks

1) MACS:
Patients participating in the MACS part of the study will not experience an additional burden due to the study. Data will be collected during standard intake and follow-up visits, and comprises of data registered in the medical files of all patients, regardless of participation in the study. The MACS is calculated on already available CT images or on CTA images obtained during the standard diagnostic workup, additional imaging for study purposes is not required.

2)Breath test:
Patients participating in the breath test part of the study will visit the hospital to perform a breath test with a 2 hour duration. We intend to combine the breath test with other hospital visits to avoid the burden of extra hospital visits. During the breath test, patients will take a high caloric drink containing 13C-butyrate. The high caloric drink might provoke the postprandial abdominal discomfort that patients usually experience. No additional discomforts or side-effect are expected of 13C-butyrate since both substances are stable isotopes. The breath test itself is non-invasive, patients are asked to fully exhale through a straw into a test-tube.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients >= 18 years

- Patients with a clinical suspicion of CMI referred to the hospital

Exclusion criteria

- Patients who are unable to give informed consent
- No available CT imaging and contraindications for CT imaging (e.g. pregnancy)
- Patients with previous mesenteric artery revascularization
- Common origin of the celiac artery and superior mesenteric artery
- Known delayed gastric emptying
- Known and untreated small intestinal bacterial overgrowth

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):	01-02-2024
Enrollment:	296
Type:	Actual

Ethics review

Approved WMO Date:	01-06-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-08-2024

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-01-2025
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	NL83632.078.23