Diagnosing Chronic Intestinal Pseudo-Obstruction with dynamic MRI motility measurements

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The aim of this study is to evaluate a dynamic MRI protocol with physiological stimulation of gastrointestinal motility as a non-invasive method for diagnosing CIPO.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON46622

Source
ToetsingOnline

Brief title
Diagnosing CIPO with dynamic MRI

Condition

- Gastrointestinal stenosis and obstruction

Synonym
bowel movement disorder, Severe bowel motility disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chronic Intestinal Pseudo-obstruction (CIPO), Dynamic MRI, Motility, Small bowel

Outcome measures

Primary outcome

The main study parameter is the response of small bowel motility to a food stimulus in CIPO patients, expressed as the ratio between the postprandial motility score and the interdigestive motility score, measured with dynamic MRI.

Secondary outcome

- To evaluate if the oral intake of a small-volume test meal is feasible in CIPO patients or if a nasogastric/duodenal tube is necessary.

- To assess if there are differences in interdigestive and postprandial motility values of CIPO patients and healthy volunteers.

- To assess if there are differences in motility of CIPO patients with a neurogenic and patients with a myogenic cause of the disease.

Study description

Background summary

Chronic intestinal pseudo-obstruction (CIPO) is a severe digestive disease caused by neurogenic and/or muscular failure of intestinal motility. The reference diagnostic test to unambiguously demonstrate CIPO is antroduodenal manometry, which is an invasive, burdensome and cumbersome test that is not widely available. Recently, dynamic MRI has emerged as a non-invasive method for evaluating small bowel motility. In this study, a novel dynamic MRI protocol with physiological stimulation will be evaluated to diagnose CIPO.

Study objective

The aim of this study is to evaluate a dynamic MRI protocol with physiological stimulation of gastrointestinal motility as a non-invasive method for diagnosing CIPO.

Study design

Eight CIPO patients will undergo a MRI protocol comprising of several baseline fasting state dynamic MRI scans and subsequently several postprandial dynamic MRI scans after taking in a liquid test meal (200 mL of Nutridrink, 300 kcal). Small bowel motility will be quantified using a validated post-processing technique, resulting in a motility score. Motility of CIPO patients will be compared with healthy volunteers that underwent a similar protocol in a previous study. Recruitment will take place via the treating physician at the gastroenterology clinic.

Intervention

All subjects will receive a test meal consisting of a standardized 300-kCal liquid meal (Nutridrink) with a volume of 200 mL. If oral intake seems not possible as assessed by the treating gastroenterologist due to a substantial risk of vomiting, a nasogastric or duodenal tube will be placed for intake of the test meal.

Study burden and risks

The ingestion of the test meal in this patient group can induce nausea and vomiting with a small risk of aspiration. To prevent this, patients will be screened by a clinician with experience treating this group and the risk of vomiting will be estimate, if this is substantial a nasogastric tube will be placed. This can be uncomfortable but has minimal risks, a method (Cortrak®) without need for imaging with ionizing radiation will be used. Risks for the MR examination are minimal, MRI is a diagnostic procedure without direct therapeutic effects. The time burden will be a one-time visit early in the morning of maximally 1,5 hours.

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

Willing to give informed consent
Willing to undergo MRI
18 years or older
Willing to receive a small-volume test meal either orally or via a nasogastric/duodenal tube
Diagnosed with CIPO based on symptoms of intestinal occlusion and findings at antroduodenal manometry compatible with CIPO (abnormal propagation of phase 3 or abnormally low contraction amplitudes)

Exclusion criteria

Being unable to give informed consent
Inability to hold breath for 20 seconds
Contraindications to undergo MRI (certain neuroclips, pacemaker, claustrophobia, pregnancy)
Contraindication for ingredients in the test meal (Nutridrink Juice style apple)
Substantial risk of vomiting after intake of the test meal (which cannot be solved by placing a nasogastric or duodenal tube), as assessed by a clinician with experience treating this patient group

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2018
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO

Date:	30-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL63706.018.18