Dynamic 3D MRI for detection, quantification and evaluation of small bowel motility

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

Summary

ID

NL-OMON45985

Source
ToetsingOnline

Brief title
MOTAC

Condition

- Gastrointestinal inflammatory conditions

Synonym
bowel movement, Gastro-intestinal motility

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: CTMM is een Nederlands publiek-privaat samenwerkingsinitiatief

Intervention

Keyword: compressed sensing, dynamic MRI, Motility, small bowel

Outcome measures

Primary outcome

This pilot study is to assess whether these 3D dynamic MRI acquisition and post-processing techniques can be used as a tool to detect and quantify small bowel motility. The main outcome parameter is detection of small bowel motility.

Secondary outcome

Secondary outcome parameter is the validation and comparison of the two methods by demonstrating the effects of motility modification.

Study description

Background summary

Small bowel motility disorders are frequently found in a variety of gastro intestinal diseases, e.g. irritable bowel syndrome (IBS), inflammatory bowel disease (IBD), chronic idiopathic intestinal pseudo obstruction (CIIP) and ileus. Dynamic Magnetic Resonance Imaging (MRI) is playing an evolving role in the assessment of bowel motility in patients with inflammatory bowel disease (IBD). Recently new developed 2D and 3D dynamic MRI techniques have been proposed for the assessment of small bowel motility.

Study objective

The aim of this study is to evaluate 3D dynamic MRI as a diagnostic tool in the assessment of small bowel motility using several new acquisition and post-processing techniques. For the acquisition of the MR images the SPatial Modulation of Magnetization (SPAMM) sequence and the Motility Accelerating (MotAc) sequence will be used. To accelerate the acquisition of the scans, two acceleration techniques (sensitivity encoding (SENSE) and compressed sensing (CS)) will be used and evaluated for acquiring scans with a higher temporal resolution. The registered motion is quantified using two analysis techniques.

A scale-space based analysis will be used for the images acquired with the SPAMM sequence, allowing quantification of the motility frequencies and amplitudes. An optical flow analysis will be used for the images acquired with the MotAc sequence to produce a motility *map* and to provide a surrogate for motility. Conditions will be maintained equal during scan sessions to test the reproducibility of the methods.

Study design

42 consecutive healthy volunteers with no history of gastrointestinal disorders will be included in this prospective study. All volunteers will undergo a MRI examination after 4 hours of fasting and minimal bowel preparation. Six subjects will be administered a spasmolytic agent (scopolaminebutyl) to alter the bowel motility. These scans are used for assessing the MRI acceleration techniques. Thirty subjects are presented with a *food challenge* after the first baseline scans. After ingestion of the motility modifying substance the subject will be scanned several times in the following 30 min. Recruitment of volunteers will take place by means of advertising.

Study burden and risks

Risks for the subjects undergoing the MRI examination are minimal. MRI is a diagnostic procedure so there are no direct therapeutic effects. Exclusion criteria for this study are an age of less than 18 years or more than 45 years and the inability to hold breath for 25 seconds. Other exclusion criteria include the contraindications to undergo MRI; pacemakers, claustrophobia and pregnancy. Further exclusion criteria exist regarding the use of intravenous injection of Scopolaminebutyl, including glaucoma or severe cardiac arrhythmia, in those individuals scheduled for administration of this drug. Possible side effects of Scopolaminebutyl are dry mouth and blurred vision. There is no benefit for the healthy volunteers, except for a remuneration (70 euros) and reimbursement of travel expenses. The outcomes of this study can be used in evaluating the clinical utility of this method. If these methods prove to be a validated tool in detecting small bowel motility, future clinical studies will be planned.

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

Healthy, human volunteers who are willing to undergo minimal bowel preparation and magnetic resonance imaging (MRI) and who are willing to give informed consent.

Exclusion criteria

An age of less than 18 years or more than 45 years, subjects who were unable to give informed consent, the inability to hold breath for 25 seconds, history of abdominal surgery, gastrointestinal diseases or current gastrointestinal symptoms. Furthermore exclusion criteria are (relative) contraindications to undergo MRI; pacemakers, claustrophobia and pregnancy. For the subjects participating in the first part of the study additional exclusion criteria are (relative) contraindications for the use of intravenous injection of butylscopolamine. For the subjects participating in the second part of the study additional exclusion criteria are contraindications for the use of Nutridrink Juice style Apple (the motility modifying substance).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2016
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	16-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	01-09-2017
Application type:	Amendment
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	NL54884.018.15