Altered brain processing of rectal sensation in children with functional fecal incontinence.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON34690

Source
ToetsingOnline

Brief title
fMRI and rectal barostat

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
functional constipation and fecal incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Pilot studie (MRI) wordt betaald middels een subsidie van de Maag-Lever-Darm-Stichting

Intervention

Keyword: constipation, fecal incontinence, functional MRI, rectal barostat

Outcome measures

Primary outcome

The cerebral regions and level of brain activity in children with FC and FNRFI

during rectal sensation of urge to defecatie.

Secondary outcome

Differences in cerebral activity between FC and FNRFI.

Study description

Background summary

Fecal incontinence, unintentional passage of stool, is a common condition in children, with a prevalence of 3% in a Dutch population-based study. It is a source of distress and concern for children and their families. Functional fecal incontinence can be subdivided in constipation-associated fecal incontinence as described by the ROME III criteria as functional constipation (FC) and functional non-retentive fecal incontinence (FNRFI). A subgroup of children with FC and FNRFI remains symptomatic up to adolescence or young adulthood. A clear relation between treatment failure and ano-rectal parameters has never been identified. Understanding the underlying physical abnormalities of these continence disorders is crucial for the development of better treatment strategies.
Children with functional fecal incontinence (both FC and FNRFI) often report *loss of defecatory urge sensation*. Therefore diminished rectal sensation was suggested a contributing factor. However, when examining rectal sensation with pressure-controlled rectal distension no abnormal afferent sensation could be identified in children with FC and FNRFI. Furthermore, the involuntary internal anal sphincter relaxes sufficiently when rectal distension occurs in children with FC and FNRFI. However, the role of the voluntary external anal sphincter in the pathogenesis of fecal incontinence in these patients, is uncertain. Clearly, continence depends also on cerebral control of the external sphincter and pelvic floor muscles. We propose that this cerebral control is impaired, with altered or diminished brain processing of rectal urge sensation.
Increasing studies have been conducted to unravel the brain processing of visceral sensation in adults with functional gastrointestinal disorders using

functional magnetic resonance imaging (fMRI). fMRI studies in adults showed that the anterior cingulated cortex, insular cortex, thalamus and primary somatosensory cortex are activated during rectal sensory stimuli. fMRI in combination with rectal distension has never been performed in the pediatric population.

Study objective

Our hypothesis is that the brain processing of rectal sensation is impaired in children with functional fecal incontinence, leading to reduced cerebral activity during rectal distension.
We will perform a pilot study using fMRI in combination with rectal barostat to measure regional cerebral activity in response to rectal distension to determine (1) if fMRI can detect cerebral activity in children with functional fecal incontinence during sensation of urge to defecate; and (2) if differences in cerebral activity exist between FC and FNRFI patients.

Study design

In this observational pilot-study, functionale MRI testing will be performed simultaneously with rectal barostat.

Baseline measures
At intake, a standardized interview will be conducted to determine demographic data, defecation pattern and defecation related behavior. Abdominal and rectal examination will be performed to evaluate the presence of fecal mass in the rectumm this is part of standard medical care.
Colonic transit time will be measured. This will be performed as previously prescribed and is considered a standard diagnostisc procedure to differentiate between FC and FNRFI. After discontinuation of oral and rectal laxatives, 1 capsule with 10 radio-opaque markers will be ingested on 6 consecutive days. On day 7, a single abdominal radiograph will be obtained and the number of markers will be counted in the right, left and rectosigmoid colonic regions based on identification of bony landmarks and gaseous outlines.

Rectal barostat
A rectal barostat test will be performed as previously reported. A non-compliant polyethylene balloon with a maximum volume of 500 ml is connected to a computer-driven barostat device. The balloon is fixed on a 8 meter long silicone catheter thereby the barostat device can be located in a different area than the MRI scanner. The lubricated balloon will be introduced manually into the rectum.
Prior to the pressure-controlled distension protocol, the balloon is unfolded by volume increase until a volume of 150 ml was reached. The inflated balloon is then pulled back against the pelvic floor. After deflation, the minimal distension pressure (MDP) will be determined by stepwise increasing the

intra-balloon pressure (1 mmHg steps of 1 minute).
A 5 minute period with a deflated balloon is followed to allow for rectal adaptation. An intermittent distension protocol with step-wise increases of 3 mmHg to 24 mmHg above MDP (i.e. 6 mmHg above the 95th percentile of urge to defecate in FC) will be used to determine rectal sensation. Each step lasts 60 seconds with intervals of 60 seconds at MDP. At 30 seconds rectal sensation will be scored for each step. An ordinal scale from 0-5 is used to score sensation: 0=no sensation, 1=first sensation, 2=urge to defecate, 3=moderate urge to defecate, 4=severe urge to defecate, 5=pain.

MRI scanning
After the distension protocol the subject will be positioned in the MRI scanner. Functional scanning will be performed by a 3.0 T Intera fMRI scanner (Philips Medical Systems) using blood oxygenlevel dependent (BOLD) contrast. In addition, to obtain anatomical information for each subject, high resolution anatomical scans will be performed for co-registration of the fMRI data.
The rectal pressure at which urge to defecate is felt during the first distension protocol will be used during two scanning sessions of 5 stimulations consisting of repetitions of 30 seconds of rectal stimulation followed by 30 seconds of rest with MDP. Between the two sessions there will be 5 minute resting time without scanning.

Study burden and risks

There are no risks related to rectal barostat and fMRI research.
The burden of the rectal barostat is considered minimal. The introduction of the rectal catheter can be uncomfortable, therefore an extensive preparation of the patient will take place. Rectal distension can cause abdominal pain or cramps. However the pressure on the rectum will be lower compared to thresholds of abdominal pain in earlier studied children, therefore in current study chances are low that abdominal pain occurs. If a child experiences abdominal pain the study will be ended.
MR imaging is a non-invasive modality. All patients will receive extensive information about the MRI procedures beforehand. Extensive coaching and preparation of the children and adolescents to prevent stress and anxiety will be part of the standard procedures: the adolescents get the opportunity to get acquainted with the MRI scanner and its procedures before the real scan session starts, in order to prevent stress and anxiety. There will be minor discomfort caused by having to lie absolutely still for several minutes and being fixed in a small space. Therefore a rest period is added to the protocol and subjects suffering from claustrophobia are excluded from participation. Considering the coaching and preparation of the adolescent patients beforehand, we consider the burden of this procedure to be minimal. Since MR imaging is considered a safe standard medical procedure, also in children and adolescents, we evaluate the risks associated with MR scanning to be negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Adolescents between 12-18 years old who suffer from fecal incontinence for at least 2 years and who fulfill the ROME III criteria for functional constipation or functional non-retentive fecal incontinence will be eligible for enrolment.;Functional constipation is defined by at least 2 of the following criteria: 1) spontaneous defecation frequency <3 per week, 2) fecal incontinence episodes *1 per week, 3) retentive posturing, 4) painful or hard bowel movements, 5) passage of large diameter stools and 6) presence of large fecal mass in the rectum. ;Functional non-retentive fecal incontinence (FNRFI) is defined by all of the following criteria: 1) defecation into places inappropriate to the social context at least once per month, 2) no evidence of an inflammatory, anatomic, metabolic, or neoplastic process that explains the subject*s symptoms, 3) no evidence of fecal retention.
All study subjects and/or the parents should sign informed consent before enrolment.

Exclusion criteria

Patients with 1) organic causes of constipation, including Hirschsprung*s disease, muscle disorders, prior recto-anal surgery, spina bifida, mental retardation or hypothyroidism, 2) intercurrent illness or active colitis, 3) known allergy to latex or polyethylene, 4) incapable to verbally cooperate or 5) claustrophobia will be excluded from the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

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	NL30774.018.10