Anorectal continence and defecation reflex tests: pilot study

Published: 04-11-2011
Last updated: 04-05-2024

1. To investigate whether we are able to initiate and measure the continence and defecation reflex in healthy human volunteers with our new method. 2. To compare the results of these measurements with those of existing techniques.3. To investigate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON34178

Source
ToetsingOnline

Brief title
Anorectal reflex tests: pilot study

Condition

- Anal and rectal conditions NEC

Synonym
Constipation and incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: inkomsten van een patent van de hoofdonderzoeker

Intervention

Keyword: Anorectal reflex, Continence, Defecation, Receptor

Outcome measures

Primary outcome

Initiation of the defecation and the continence reflex with the new test

method.

Secondary outcome

Comparison of the new method with existing methods to measure the anorectal

reflexes.

Observations that suggest that the anorectal reflexes are cross-linked, i.e.

that unilateral stimulation leads to a bilateral response.

Study description

Background summary

Anal incontinence and/or constipation are debilitating conditions that affect a substantial portion of the general population. Evaluation of the neurophysiological function of the anorectum is important to diagnose the condition and to determine treatment strategy.

Current tests to evaluate the neurofysiologic function of the anorectum consist of electrofysiologic tests and manometric tests. These tests are time-consuming and are not always correlated with the clinical symptoms. Also, active co-operation by the patient is required, which is difficult when the patients are young children.

With our novel method, the receptors in the anal canal can be stimulated whilst measuring pressure in the anal canal and the rectum. In this manner, the neurophysiologic assessment of the anorectum can be performed in less time, with greater accuracy and with less burden on the patient.

Before testing the novel method in patients, it needs to be tested in healthy human volunteers to validate the method and to compare it to current tests.

Study objective

1. To investigate whether we are able to initiate and measure the continence and defecation reflex in healthy human volunteers with our new method.
2. To compare the results of these measurements with those of existing techniques.
3. To investigate whether the left and right reflex pathway function with or without cross linking.

Study design

All volunteers will be seated on a toilet seat as they undergo the following measurements (in chronological order):

a. Anal electrosensibility test (standard clinical test)
A small catheter with electrodes will be inserted into the anal canal and on every cm the anal sensitivity will be measured (The minimal stimulation been felt by the person)4.

b. The continence reflex test (novel test, see further on in this section)
On different levels left or right in the anal canal the surface will be stimulated and simultaneous the anal pressure on different levels will be recorded.

c. The defecation reflex test (novel test, see further on in this section)
On different levels left or right in the anal canal the surface will be stimulated and simultaneous the anal and rectal pressure on different levels will be recorded.

d. Left and right anorectal reflex tests (novel test, see further on in this section).
The left or right side of the anal canal will be selectively stimulated whilst pressures in the anal canal and rectum are measured.

e. Sphincter pressure test (standard clinical test)
During relaxation, squeeze and push action of the patient anal and rectal pressure will be measured.

f. Balloon retention test (standard clinical test)
A balloon will be inserted into the rectum and slowly (1 ml/second) filled with water of 37*C water. Patients are asked to mention when they do feel rectal filling sensations until maximal tolerable pressure, then the balloon will be deflated rapidly. During this simulating solid stool in the rectum the

pressures in the anal canal and the rectum will be recorded.

g. Rectal infusion test (standard clinical test)
Without a balloon water of 37*C will be inserted slowly (1 ml/second) in the rectum. Fecal continence for liquid stool be tested. A healthy person can easily keep 1,5 liter into the rectum without incontinence. During this filling pressures in the anal canal and the rectum are recorded.

Study burden and risks

The novel method combines two existing methods which do not carry any risks. Therefore, there is no risk to the participants.

The burden of participation consists of elektrodes and a small balloon being placed in the anal canal during one session of two hours. This may be felt as an unusual sensation. Also, some discomfort of the anal region may be felt up to 15 minutes after the study has ended.

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

Men and women
>= 18 years old

Exclusion criteria

- history of anorectal problems,
- history of trauma or surgery on the gastrointestinal tract / lower abdominal surgery, except appendectomy via laparoscopy or grid incision
- a positive questionnaire for anorectal problems

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	04-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL34072.042.10