The physiology of the anorectum, a pilot study

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Our main objective is to investigate the mechanisms that regulate anorectal physiology.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON45567

Source
ToetsingOnline

Brief title
Physiology of the anorectum

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Constipation, Fecal obstruction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anorectal Function Tests, Anorectum, Defecation

Outcome measures

Primary outcome

Because we hypothesize that the physiological regulatory mechanisms of anorectal function are located in the anal (sub)mucosa, we will compare all the physiological parameters obtained during anorectal function tests performed under two conditions: with an active superficial anal mucosa, and after its inactivation. In this way we will be able to indicate the regulatory factors, and also prove that that they are located in the anal mucosa or submucosa, which will be the outcome of this study.

Secondary outcome

Not applicable.

Study description

Background summary

Constipation is currently one of the most common digestive complaints in the Western world. Since the physiology of the defecation process in healthy people is not clear, it is still impossible to efficiently diagnose and treat constipation.

Study objective

Our main objective is to investigate the mechanisms that regulate anorectal physiology.

Study design

This study is an invasive intervention study in healthy human subjects.

All participants will undergo two times the following test session, existing of the following standard anorectal function tests:
• The anal electro sensitivity test

• The anal pressure test
• The recto-anal inhibition reflex test
• The balloon retention test
• The defaecometry test
• The Barostat test
• The rectal infusion test

During the first session, the participants will be measured without applying local anesthesia. Prior to the identical, second test session we will apply local anesthesia to the anal canal of the participant. The anesthetic will be applied randomized: 20 participants will receive a placebo, which does not contain the anesthetic component.

Intervention

During the second testsession, we will apply the local anaesthetic or placebo to the anal canal of the participant. After approximately 15 minutes, we will start with the anorectal function tests.

Study burden and risks

There are no risks associated with study participation.

All anorectal function tests are standard tests used internationally, performed by an experienced nurse and/or have been previously approved by the medical ethics committee of the University Medical Center Groningen.
The local, superficial anesthetic that is used to anesthetize the anal canal, is a generally accepted anesthetic. However, we will inform the participants about a possible mild incontinence for approximately four hours after the test session, which is very unlikely because all participants need to use an enema the day before undergoing the anorectal function tests.

With the results of this study, new insights in the physiologic function of the anorectum will be gained. Having a complete view of the regulatory mechanisms of defecation process in healthy subjects, it will be possible to recognize any abnormalities in these defecation mechanism in patients with defecation problems. In this way, improvement of the existing diagnostics and treatment of chronically constipated patients will be possible.

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

All subjects must be aged > 18 years.

Exclusion criteria

A potential subject with self-report of bowel problems in a checklist, medical history of congenital abnormalities of the anorectal area, neurological dysfunction, current pregnancy and/or trauma or surgery on the gastrointestinal tract or pelvic floor with a possible influence on anorectal function, will be excluded from analysis.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	10-04-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-01-2019
Application type:	Amendment
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	NL58969.042.16