Functional Anal SphinctEr ultrasound - An explorative study

Published: 28-03-2023
Last updated: 29-04-2024

Assessment and quantification of the function of the external anal sphincter by means of 4D ultrasound.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON53496

Source
ToetsingOnline

Brief title
FASE

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Sphincter dysfunction, sphincter laesion

Health condition

Sfincterletsel

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Maatschap Gynaecologie

Intervention

Keyword: Anal Sphincter, Functional, Ultrasound

Outcome measures

Primary outcome

Primary outcome is to determine the added value of functional assessment of the external anal sphincter by means of 4D ultrasound strain measurements in diagnosis and treatment decision making for patients with anal sphincter dysfunction and/or fecal incontinence.

Secondary outcome

Secondary outcomes include:

Relation between 4D ultrasound and other measurements

Differences in EAS function and anatomy between groups

Relation between physical complaints and the amount of anal trauma.

Study description

Background summary

Rationale:
Fecal incontinence (FI) is the involuntary discharge of liquid or solid stools. The estimated prevalence of FI in noninstitutionalized US adults is 8.3%. FI has a high impact on the quality of life. A 2009 cross-sectional study of 154 patients (27 male) with FI using the Fecal Incontinence Quality of Life Scale reported that more than 22% of patients had their QoL affected severely (on a scale of 1= very affected and 4 = not affected) by FI. The pelvic floor muscles that maintain faecal continence are the internal anal sphincter (IAS), external anal sphincter (EAS) and puborectalis muscle (PRM).

Main causes voor trauma, and therefore disfunction of the EAS is obstetric anal sphincter injury (OASI) or surgical intervention due to (recurring) perianal fistula.

Current assessment of the EAS is done by manometry, digitization or 2D/3D ultrasound based on anatomical parameters.

Hypothesis: We hypothesize, that accurate diagnosis of (trauma to) the external anal sphincter can be improved by means of 4D functional ultrasound

Study objective

Assessment and quantification of the function of the external anal sphincter by means of 4D ultrasound.

Study design

prospective cross-sectional comparison study

Study burden and risks

We ask the volunteers and patients to visit the ZGT hospital at least one times (in case of effectiveness of for instance pelvic therapy follow-up is necessary).

During these visits of approximately 30 minutes, patients will undergo transperineal ultrasound examination and fill in (homemade and dedicated (PDFI-20)) questionnaires. The questionnaires do not relate to sexual wellbeing and the ultrasound is non-invasive.

Contacts

Public
Ziekenhuisgroep Twente

Geerdinksweg 141
Hengelo 7555DL
NL
Scientific
Ziekenhuisgroep Twente

Geerdinksweg 141
Hengelo 7555DL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

o Good knowledge of Dutch language
o Women >=18 years of age
o Signed informed consent

Patients:
o Previous anal sphincter injury (OASI)

Additional inclusion criteria for each substudy will be described in the appendices.

Exclusion criteria

We only list general exclusion criteria for the healthy controls, since patient characteristics will be sub-study dependent.
• Known injury to the anal sphincter
• Symptoms of pelvic floor dysfunction (e.g. urinary of fecal incontinence, obstipation, prolapse feeling, pelvic pain)

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-04-2023
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-07-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL83010.091.22