Functional Ultrasound and the success of Sacral NeuroModulation in Fecal Incontinence

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

Summary

ID

NL-OMON57156

Source
ToetsingOnline

Brief title
SNM study

Condition

- Gastrointestinal motility and defaecation conditions
- Gastrointestinal therapeutic procedures

Synonym
fecal incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen
Source(s) of monetary or material Support: Een interne ZGT Wetenschapsbeurs

Intervention

Keyword: fecal incontinence, Sacral neuromodulation, strain, transperineal ultrasound

Outcome measures

Primary outcome

Difference in muscle strain before and after SNM placement.

Secondary outcome

• Difference in myofeedback (MAPLe) before SNM and after SNM placement.

• Correlation between symptom improvement (PGI-I, diaries, FIQL and ODS) and anal sphincter functional measurements (strain and MAPLe).

• Difference in anal sphincter functional strain measurements between patients with fecal incontinence and without fecal incontinence (data of the previous FASE study*)

• Difference in anal sphincter functional strain measurements and anatomy between patients with successful (>50% complaint reduction) and without successful SNM test period.

* The patients in the previous FASE study all agreed that their data could be used for additional pelvic floor research in the consent form.

Study description

Background summary

Constantly wondering where the nearest toilet is, no longer daring to go on group outings and no longer wearing white pants. This is daily practice for people with fecal incontinence (FI), a total of 3-10% of the population, more often women than men. Due to this major negative impact on quality of life, FI

is known as one of the most disabling physical complaints.

The development of FI is multifactorial, but the function of the anal sphincter (AS), one of the pelvic floor muscles, plays the most important role. The AS can lose its function (partly) due to disturbed control (neurological) or due to damage to the AS, for example a total rupture during childbirth.

If primary care (pelvic physiotherapy, absorbent products and lifestyle adjustments) and non-operative second-line care (percutaneous posterior tibial nerve stimulation, colonic irrigation and anal tampons) do not provide sufficient relief, sacral neuromodulation (SNM) can be used. SNM is a kind of pacemaker for the pelvic floor muscles: An electrode wire is inserted into the sacral spine (S3), after which local nerve stimulation (pudendal nerve) triggers a motor response, including contraction of the pelvic floor and the AS. However, the exact mechanism behind the working of SNM is unknown.

To determine whether the treatment with SNM is successful, patients are asked to keep a diary about their complaints. The success of SNM is determined subjectively based on a diary: SNM is considered successful with >=50% improvement in complaints. This improvement is achieved in 70-80% of patients, which means that these people have a large and lasting gain in quality of life. However, it also means that 20-30% of patients retain their complaints and that with "successful" SNM FI complaints may still exist, but to a lesser extent, because 100% improvement in complaints is almost never seen. There is therefore still room for improvement in the care of patients with FI. Better understanding of the mechanisms behind the success and failure of SNM for FI is essential.

Study objective

The aim of this study is to describe the difference in function of the anal sphincter, measured with functional ultrasound (4D transperineal ultrasound [TPUS] derived strain), before and after SNM as a treatment for fecal incontinence.

Secondary objectives:

• Describe the difference in function of the AS, measured with functional ultrasound, between patients with and without fecal incontinence.
• Describe the relationship between function of the anal sphincter (ultrasound strain measurements) and the patients' complaints (validated questionnaires and diaries).
• Describe the relationship between the function of the anal sphincter based on ultrasound strain measurements and function of the anal sphincter based on anal myofeedback measurements.
• Describe the relationship between the function of the anal sphincter based on TPUS strain measurements and anatomy based on endo-anal ultrasound and 4D

ultrasound.
• Describe the difference in the function of the anal sphincter (4D TPUS strain) between patients in whom the SNM treatment for fecal incontinence is successful (>=50% improvement in complaints) and not successful.

Study design

This prospective, observational study will analyze the feasibility of strain 4D TPUS derived muscle strain measurements in the assessment of anal sphincter function before and after SNM. Twenty patients will be enrolled in the study. The cohort will follow the standard work flow for SNM with the addition of 4D functional TPUS derived strain measurements prior to the SNM treatment (maximal FI complaints) and after the SNM treatment (minimal FI complaints). At these moments the in standard care executed functional measurement of electromyography (EMG) (myofeedback [MAPLe],) will be obtained to validate the strain measurements. Upon inclusion the demographic information is collected and throughout the study period the clinical information that is gathered in diaries and questionnaires will be obtained for the study (PGI-I, FIQL and ODS).

Study burden and risks

There is a limited burden for patients to participate in this study. The first burden is travelling, all participants need to go to the ZGT-hospital (Hengelo) for the 4D ultrasound scan and MAPLe measurement prior to SNM test period, after SNM test period and after final SNM placement. The second and final burden of this research is based on filling in questionnaires on general health and pelvic floor symptoms at the aforementioned timepoints. To lower the burden, we aim to let the study visits take place adjacent to visits of standard clinical care and in consultation with the patient. Moreover, considering the large impact on the Quality of Life (QoL) of FI, we expect that most patients are very willing to participate to this study in order to improve the FI care.

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

- Complaints of fecal incontinence and eligible for sacral neuromodulation
- Able to read and understand Dutch.
- Signed informed consent
- Female

Exclusion criteria

<18 years old

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-12-2024
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Philips EPIQ7 ultrasound system + Novuqare MAPLe system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL87536.100.24