Value of 3D Anal Manometry in anal Fistula Surgery: AMFI study

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To investigate if the pre- and/or postoperative 3D-HRAM and 3 dimensional endo-anal ultrasound (3D-EAUS) might be a predictor for fecal incontinence after fistulotomy by evaluating changes in anorectal function and correlate this with the Fecal...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Procedural related injuries and complications NEC
Study type	Observational invasive

Summary

ID

NL-OMON50540

Source
ToetsingOnline

Brief title
AMFI study

Condition

- Procedural related injuries and complications NEC
- Gastrointestinal therapeutic procedures

Synonym
fistula, fistula in ano, perianal fistula

Research involving
Human

Sponsors and support

Primary sponsor: Heelkunde
Source(s) of monetary or material Support: Proctos Kliniek

Intervention

Keyword: anal fistula, endoanal ultrasound, fistulotomy, manometry

Outcome measures

Primary outcome

1. Changes in anorectal function measured with 3D-HRAM before and after fistulotomy

2. Changes in continence and soiling between preoperative and 4 and 12 months postoperative. Measured with patient reported outcome measurements: FiQL, Wexner and ProctoPROM.

3. Correlation between 1 and 2

Secondary outcome

1. To analyze sphincter defects with the EAUS examination and correlate this with the pressure-profile measured by 3D-HRAM.

2. To establish possible prognostic factors for deterioration in anorectal function and fecal incontinence in patients who underwent fistulotomy

Study description

Background summary

The surgical management of anal fistulae remains challenging as consequences of anal surgery can cause profound fecal incontinence (FI) and impair experienced quality of life. Therefore fistulotomy is restricted to low fistulas. But even then, FI may occur. Prospective conventional anorectal manometrie (ARM) studies report that many fistula operations negatively influence anal pressures. With advanced 3D-High resolution ARM (3D-HRAM), a three dimensional pressure profile can be obtained.

Study objective

To investigate if the pre- and/or postoperative 3D-HRAM and 3 dimensional endo-anal ultrasound (3D-EAUS) might be a predictor for fecal incontinence after fistulotomy by evaluating changes in anorectal function and correlate this with the Fecal Incontinence Quality of Life Scale at 4 and 12 months.

Study design

All patients who visit our clinics with a anal fistula who will undergo fistulotomy will be asked to participate. Patients will be asked to fill in questionnaires concerning anorectal function and quality of life (Wexner, FiQL, ProctoPROM, VAS score and fistula complaints). Digital rectal examination, 3D-EAUS and 3D-HRAM will be performed pre- and postoperative.

Study burden and risks

30 min extra time during 4 months FU bezoek, 3x 5 min for questionnaires= 15 min
There is no further risk.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age between 18-80 years
- Planned to undergo fistulotomy
- Suitable for e-mail questionnaires
- Sufficient understanding of the Dutch written language (reading and writing)
- Obtained written informed consent

Exclusion criteria

- Non cryptoglandular fistulae (Crohn*s disease e.a.)
- Prior rectal radiation
- Rectovaginal fistulae
- ASA 3-4 (patients who cannot undergo surgery in our clinic)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2022
Enrollment:	73
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2021
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	NL78713.018.21