

Sexual function after 'close rectal' ileo-anal pouch.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29187

Bron

Nationaal Trial Register

Verkorte titel

PLEXLAB 2

Aandoening

Ulcerative colitis
Restorative proctocolectomy
Ileo pouch anal anastomosis
Sexual function

Colitis Ulcerosa
Proctocolectomie
Ileo anale pouch
Seksueel functioneren

Ondersteuning

Primaire sponsor: Academic Medical Center

Department of Surgery

Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary study endpoints are the difference in VPA pre- and postoperatively for the close rectal group and the difference in VPA pre- and postoperatively for the close rectal and the TME groups compared.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Standard treatment for patients with refractory Ulcerative Colitis (UC) is restorative proctocolectomy with ileo pouch anal anastomosis (IPAA). Sexual dysfunction after IPAA is common. The most systematic physical reaction to sexual stimulation is an increase in vaginal vasocongestion. This genital response can be assessed using vaginal photoplethysmography. The Plexlab study reported on 11 patients undergoing IPAA by total mesorectal excision (TME) technique. A significant reduction in vaginal vasocongestion during sexual stimulation postoperatively was reported. Subjective sexual arousal and lubrication during the experiment and reported psychological and sexual functioning pre- and postoperatively were similar. A different surgical technique, the 'close rectal' dissection, spares the mesorectum, thereby preserving small nerve fibers. We hypothesize that the close rectal technique leads to a better vaginal vasocongestion postoperatively than TME technique.

Objective:

To assess whether close rectal restorative proctocolectomy with IPAA has a better outcome regarding postoperative vaginal vasocongestion and reported psychological and sexual functioning than IPAA by TME restorative proctocolectomy.

Study design:

A single-centre comparative clinical study, performed in the Netherlands. Pre- and postoperative data will be compared with data from the earlier Plexlab study.

Study population:

Adult female patients with UC and an indication for restorative proctocolectomy or completion proctectomy with IPAA.

Intervention:

VPA measurements in the experimental laboratory of the department of Sexology.

Main study parameters/endpoints:

Primary endpoint is the difference in VPA pre- and postoperatively. Secondary endpoints are differences in feelings of sexual arousal and estimated lubrications pre- and postoperatively and difference in psychological- and sexual functioning pre- en postoperatively. The results are compared to those of the Plexlab study.

Doel van het onderzoek

The Plexlab study reported on 11 patients undergoing IPAA by total mesorectal excision (TME) technique. A significant reduction in vaginal vasocongestion during sexual stimulation postoperatively was reported. Subjective sexual arousal and lubrication during the experiment and reported psychological and sexual functioning pre- and postoperatively were similar. A different surgical technique, now commonly used in our centre, the 'close rectal dissection', spares the mesorectum, thereby preserving small nerve fibers. We hypothesize that the close rectal technique leads to a better vaginal vasocongestion postoperatively than TME technique.

Onderzoeksopzet

Patients will have one preoperative visit to the sexology outpatient clinic, where VPA measurement will take place and the questionnaires will be filled out. This will take place approximately 4 weeks preoperatively. The same measurement will be repeated one more time approximately 9 months postoperatively.

Onderzoeksproduct en/of interventie

This study is a comparative clinical study in which a group of female patients will undergo close rectal restorative proctocolectomy or completion proctectomy with IPAA. Pre- and postoperatively the patients will undergo vaginal pulse amplitude (VPA) measurements and fill out a set of questionnaires. Patient data will be compared with the patient data of the earlier Plexlab study, in which 11 patients underwent TME restorative proctocolectomy or completion proctectomy with ileo anal pouch anastomosis.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female patients;
2. >17 years and pre menopausal;
3. Ulcerative colitis;
4. Scheduled for elective restorative proctocolectomy with IPAA; or;
5. Scheduled for completion proctectomy with IPAA.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous bowel resections other than emergency colectomy;
2. Previous surgery on genitalia;
3. Non elective surgery;
4. Severe postoperative complications (e.g. anastomotic leakage, abscess, peritonitis);
5. Use of medication that might influence the sexual response (psychopharmaca, antihypertensives);
6. Diabetes Mellitus;
7. Depression (measured by Beck Depression Inventory (BDI)- Scale);
8. History of sexual abuse;
9. Pre-existence of sexual dysfunction.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 13-04-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2714
NTR-old	NTR2852
Ander register	METC AMC : 10/257
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A