

Genital and subjective sexual response in women after close rectal restorative proctocolectomy with ileal pouch anal anastomosis: a comparative clinical study

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

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON34030

Source

ToetsingOnline

Brief title

PLEXLAB II

Condition

- Gastrointestinal inflammatory conditions
- Sexual function and fertility disorders
- Gastrointestinal therapeutic procedures

Synonym

inflammatory disease of the large intestine, ulcerative colitis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: close rectal proctocolectomy, ileo pouch anal anastomosis, sexual function, ulcerative colitis

Outcome measures

Primary outcome

Primary endpoint is the difference in VPA pre- and postoperatively. The results are compared to those of the Plexlab study.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

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

Study design

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

Study burden and risks

Patients will have to bring 2 preoperative visits to the experimental laboratory of the department of Sexology. During the first visit the patient will be introduced to the laboratory where the VPA measurements will be demonstrated. In addition, a set of questionnaires must be completed. The second visit will include the VPA measurements during visual and vibrotactile sexual stimulation. Postoperatively the patient will bring one more visit to the laboratory, where the VPA measurements will be repeated and another set of questionnaires will be filled out. There is no risk or benefit involved for the patients.

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

Female patients

>17 years and pre menopausal

Ulcerative colitis

Scheduled for elective restorative proctocolectomy with IPAA; or

Scheduled for completion proctectomy with IPAA

Exclusion criteria

*Previous bowel resections other than emergency colectomy

Previous surgery on genitalia

Non elective surgery

Severe postoperative complications (e.g. anastomotic leakage, abscess, peritonitis)

Use of medication that might influence the sexual response (psychopharmaca, antihypertensives)

Diabetes Mellitus

Depression (measured by Beck Depression Inventory (BDI)- Scale)

History of sexual abuse

Pre-existence of sexual dysfunction

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2010
Enrollment:	18
Type:	Anticipated

Ethics review

Approved WMO	
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	NL34346.018.10