

Is sexual dysfunction in women after restorative proctocolectomy with ileal pouch anal anastomosis (IPAA) caused by autonomic pelvic nerve damage?

Submission date 20/07/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/08/2009	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MEC 03/281 # 04.17.0283

Study information

Scientific Title

A prospective clinical trial of autonomic pelvic nerve damage in women with sexual dysfunction after restorative proctocolectomy with ileal pouch anal anastomosis (IPAA)

Acronym

Plexlab

Study objectives

Sexual dysfunction after ileal pouch anal anastomosis (IPAA) is common. The most systematic physical reaction to sexual stimulation is an increase in vaginal vasocongestion. Damage to the autonomic nerves disrupt this process. Genital response can be assessed by vaginal pulse amplitude using vaginal photoplethysmography. To date, little is known about the contribution of damage to the pelvic autonomic nerves. Aim of this prospective study was to assess whether IPAA is associated with autonomic pelvic nerve damage and changes in subjective indices of sexual function in women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medische Ethische Commissie approved on the 25th February 2004 (ref: MEC 03/281 # 04.17.0283)

Study design

Single-centre prospective clinical trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Ulcerative colitis

Interventions

During sexual stimulation (visual and vibrotactile) changes in vaginal vasocongestion were measured by vaginal photoplethysmography. This is currently the most sensitive, specific and reliable instrument for measuring vaginal vasocongestion. Vaginal pulse amplitude (VPA) fluctuations reflect phasic changes in the blood content of the illuminated capillary bed of the vaginal wall at each heart beat, with greater amplitudes indicating increased vasoengorgement. Concurrently, quality of life (36-item short form health survey [SF-36]) and sexual functioning (Female Sexual Function Index [FSFI], Female Sexual Distress Scale [FSDS]) were assessed using validated questionnaires.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured pre- and post-operatively:

1. Difference in VPA
2. Feelings of sexual arousal and estimated lubrication
3. Difference in psychological and sexual functioning

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/04/2004

Completion date

01/01/2006

Eligibility**Key inclusion criteria**

1. Female patients
2. Planned for a laparoscopic proctocolectomy with IPAA
3. Aged greater than 18 years
4. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

15

Key exclusion criteria

1. Prior midline laparotomy
2. Operation on genitals
3. Diabetes mellitus
4. History of sexual abuse
5. Pre-existent sexual dysfunction
6. Use of medication with a possible effect on sexual response
7. Presence of a depressive disorder

Date of first enrolment

01/04/2004

Date of final enrolment

01/01/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Meibergdreef 11

Amsterdam

Netherlands

1100 DD

Sponsor information**Organisation**

Dutch Association for Gastroenterology (Nederlandse Vereniging voor Gastroenterologie)
(Netherlands)

Sponsor details

Prof. dr. C.B.H.W. Lamers

Postbus 657

Haarlem

Netherlands

2003RR

Sponsor type

Research organisation

Website

<http://www.nvge.nl/>

ROR

<https://ror.org/0203tey58>

Funder(s)

Funder type

Research organisation

Funder Name

Gastrostart (Netherlands) (ref: CL/MvG/20.3/PROJECT 15-2003)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration