ISRCTN92260350 https://doi.org/10.1186/ISRCTN92260350

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

Registration date
18/08/2009

Last Edited
18/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
Single-centre prospective clinical trial

Study type(s)
Treatment

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(s)
Measured pre- and post-operatively:
1. Difference in VPA
2. Feelings of sexual arousal and estimated lubrication
3. Difference in psychological and sexual functioning

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration