VMR-related pain

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26985

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Rectal prolapse, pelvic organ prolapse

Sponsors and support

Primary sponsor: Meander Medical Center, Amersfoort, The Netherlands
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The difference in pain intensity in the lower back, the lower abdomen and/or the pelvic floor before and six months after RVMR.

Secondary outcome

- To assess differences in quality of pain.
- To assess the impact of pain on daily activities.

- To investigate if the following parameters are associated with the development of pain after VMR:
o The position of the tackers intended on the promontory and the development of new-onset (or worsened) chronic pain in the lower back.
o Concomitant sacrocolpopexy
o Present complaints of OD
o BMI
o Comorbidities
o Other chronic pain
o Emotional functioning

Study description

Background summary

A proportion of the patients treated with (robot-assisted) ventral mesh rectopexy ((R)VMR) complain of postoperative chronic pain in the lower back, the lower abdomen and/or the pelvic floor. The number of patients that suffers from these symptoms however is still unknown. VMR related pain could in theory be caused by tacking the mesh to the promontory, by inserting a foreign body (mesh) into the human body or by unintended effects of the surgery itself. However, a certain number of patients also experiences pain or discomfort before surgery, possibly due to mechanical stress of the prolapsing tissues or due to OD. How preoperative pain defers from pain after VMR has never been properly monitored. The objective of this study is to investigate and compare the prevalence of pain and its characteristics before and after VMR.

Study objective

We hypothesize that in the mayority of patients there will not be any difference in experienced pain between baseline and follow-up after RVMR.

Study design

baseline, 6 weeks, 3 months, 6 months

Intervention

Robot-assisted laparoscopic ventral mesh rectopexy (RVMR)

Contacts

Public
Meander Medisch Centrum
Emma van der Schans

0338505050
Scientific
Meander Medisch Centrum
Emma van der Schans

0338505050

Eligibility criteria

Inclusion criteria

- Age ≥ 18 years.
- Indication for ventral mesh rectopexy (VMR) set by the treating physician in accordance to the current guidelines on rectal prolapse.
- Counselled for therapeutic options and given informed consent for robot-assisted VMR (RVMR) or RVMR combined with sacrocolpopexy.
- Written informed consent for observational data collection.

Exclusion criteria

- Mentally incompetent patients (unable to fulfil questionnaires).
- A medical history of pelvic radiation therapy.
- Scheduled for a redo-rectopexy.
- A medical history of previously implanted pelvic floor meshes.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7806
Other	MEC-U (verklaard als niet-WMO plichtig) : R19.008

Study results