The effect of pelvic floor muscle training on bowel symptoms after low anterior resection for rectal cancer.

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The proportion of successful patients, defined as an improvement in LARS category, will be 25% larger in the experimental group than in the control group (in which 10 % improvement is assumed).

Ethical review	Positive opinion
Status	-
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON26845

Source
Nationaal Trial Register

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Rectal cancer

Health condition

rectal cancer, bowel symptoms (fecal incontinence, urgency, frequency, fragmented defecation, soiling), Low Anterior Resection Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Research Foundation Flanders
Source(s) of monetary or material Support: FWO (Fonds Wetenschappelijk Onderzoek)

Intervention

- Movement therapy

Explanation

Outcome measures

Primary outcome

LARS-score, evaluated after 12 weeks (=16 weeks after surgery/closure ileostomy) of pelvic floor muscle training

Secondary outcome

colorectal functional outcome questionnaire, bowel diaries, the evolution of physical activity after LAR for rectal cancer, colonic manometry in a subset of patients

Study description

Background summary

Since several years, low anterior resection, with total mesorectal excision and preservation of the autonomic nerves of the pelvis has become the gold standard for rectal cancer surgery. However, this surgery affects bowel function in 60-90% of patients. These symptoms are referred to as the low anterior resection syndrome and is associated with a large negative impact on quality of life . Currently, patients only receive some anti-diarrheal medication, diet advice or the advice to wait for spontaneous improvement. Although pelvic floor muscle training is highly recommended in the treatment of bowel problems in non-cancer populations, there is still no concensus about its effectiveness in rectal cancer patients. In this research we aim (1) to evaluate if patients, who receive 12 weeks of intensive pelvic floor muscle training, have less LAS symptoms then patients who had no treatment; (2) to investigate the effect of a temporary ileostomy on LAR symptoms; (3) to assess propulsive colonic contractions and the effect of hindgut denervation on the presence of coordinated proximal to distal contractions; (4) to study the influence of LAR for rectal cancer on all physical activity levels

Study objective

The proportion of successful patients, defined as an improvement in LARS category, will be 25% larger in the experimental group than in the control group (in which 10 % improvement is assumed).

Study design

"Preoperative assessment of bowel symptoms, urinary symptoms, sexual symptoms, physical activity Assessment at 4 weeks after surgery/closure ileostomy (start PFMT for the intervention group) and at 16 weeks (primary endpoint) after surgery/closure ileostomy (end PFMT): bowel symptoms, urinary symptoms, sexual symptoms, physical activity, muscle tone/force/endurance pelvic floor muscles Follow-up assessments after 6 and 12 months: bowel symptoms, urinary symptoms, sexual symptoms, physical activity, tone/strength/endurance pelvic floor muscles Study outcomes: Control group + intervention group: LARS-score, Colorectal Functional Outcome Questionnaire, International Consulation on Incontinence Questionnaire, Female Sexual Function Index/ Interternational Index of Erectile Function, Flemish Physical Activity Questionnaire, Numeric Rating Scale, Bowel Diary, Bladder Diary, 1 hour Pad test, Evaluation pelvic floor muscles (tone, strength, endurance) Intervention group: pelvic floor muscle training (9 times in 12 weeks) "

Intervention

pelvic floor muscle training

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- patients planned for a low anterior resection for rectal cancer (TME, total mesorectal excision)
- patients who have an expected survival of at least 1.5 years
- patients who are able to come to the hospital once a week during the complete treatment period (12 weeks)
- patients with a minimal LARS score of 21/42

Exclusion criteria

- having a HARTMANN procedure, abdominiperineal excision or transanal microsurgical resection or sigmoïd resection
- patients with neurological conditions
- patients with cognitive problems
- patients with preoperative fecal incontinence
- patients who have had precious pelvic surgery, previous pelvic radiation or LAR for non-cancer reasons

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Single
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Treatment

Recruitment

EU

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-01-2017
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-01-2017
Application type:	First submission

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	NL6227
NTR-old	NTR6383
Other	Number Ethical Committee of University Hospitals Leuven S59761

Study results

Results posted: 06-03-2024

Actual enrolment: 125

Summary results

"The main study of this project was a multicentre randomized controlled trial, investigating the effectiveness of PFMT on low anterior resection syndrome. Initially, 120 patients were foreseen to be included. Eventually, a total of 104 patients was recruited due to time- and COVID-19-restrictions and a lower than predicted drop-out rate. Patients were randomly assigned to an intervention group (n = 50, receiving 12 weeks of PFMT, including pelvic floor muscle exercises, advice, biofeedback, electrical stimulation, bowel training and balloon training) or a control group (n = 54, not receiving PFMT, nor any of the abovementioned treatment modalities). The nine PFMT-sessions were started one month after TME/stoma closure and consisted of a variety of techniques among which pelvic floor muscles exercises, balloon training, biofeedback and evacuation techniques. Regarding bowel symptoms, the LARS- and COREFO- questionnaire, the Numeric Rating Scale (NRS) regarding the subjective bother of bowel symptoms as well as stool diary items were analysed. The SF-12 questionnaire was analysed in relation to the quality of life. All of these outcome measures were assessed at 1, 4, 6 and 12 months after TME/stoma closure. The results demonstrated the effectiveness of PFMT in reducing the proportion of patients with major bowel complaints as per categorized LARS-scores. Stool frequency, incontinence and clustering were also positively influenced by PFMT. Moreover, PFMT ensured a faster recovery process regarding those bowel complaints up to six months after surgery/stoma closure. As regards to quality of life scores, no significant results were found.

A 2nd study was conducted to investigate whether bowel symptoms related to LAR for RC could be sufficiently well evaluated by the LARS-questionnaire or the COREFO-questionnaire, compared to the stool diary. Patients were asked to fill out the stool diary and the LARS- and COREFO-questionnaire at 1, 4, 6 and 12 months after TME/stoma closure. Data from a subgroup of 95 patients of the previously mentioned RCT was analysed. Following items were significantly correlated between the LARS-/COREFO-questionnaire and the stool diary: anal incontinence for faeces and frequency of bowel movements. Furthermore, items on soiling were significantly correlated between the COREFO-questionnaire and the stool diary. No significant association was found with the information provided by the stool diary for either questionnaire on items on clustering of bowel movements and urgency. Lastly, overall moderate associations were found between the questionnaires and the stool diary, although the amount of overlapping information was rather limited.

Finally the progression of all PA levels (total, sport, occupational and household) was investigated over time, together with the exploration of possible predictive factors for a decrease in those PA levels. Patients were asked to fill out the Flemish Physical Activity Computerized Questionnaire (FPACQ) and the LARS- and COREFO-questionnaire regarding the preoperative period and at 1, 4, 6 and 12 months after TME/stoma closure. Results from the 125 included RC patients showed that total physical activity levels remained significantly lower than preoperative values up to 12 months postoperatively. Furthermore, occupational and sports physical activity levels remained significantly lower until 6 and 4 months

postoperative, respectively. Predictive factors for decreased physical activity levels at a specific timepoint were: younger age and no stoma (total physical activity, 1 month), low/mid rectal tumour, no stoma, non-employed status (total, 4 months), higher COREFO-scores (occupational, 4 months) and non-employed status (total, 12 months)."

Baseline characteristics
Mean age was 58.49 years (SD 11.07), 66.40% of patients were males. Median BMI was 24.58 kg/m².

Participant flow
"For the main study (RCT): 370 patients assessed for eligibility, of which 104 patients could be enrolled and randomized: 50 in the experimental group (pelvic floor muscle training) and 54 in the control group (no training). Three patients in every group

Adverse events
No adverse events

First publication
22-01-2021

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