Pelvic Floor rehabilitation to improve functional Outcome and quality of life after surgery for Rectal CancEr: a randomized trial.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27444

Source
Nationaal Trial Register

Brief title
FORCE-trial

Health condition

Rectal cancer; pelvic floor rehabilitation (PFR); fecal incontinence, Low Anterior Resection Syndrome (LARS), low anterior resection, TME.

Sponsors and support

Primary sponsor: UMCG, MCL, Isala Kliniek Zwolle
Other institutions invited
Source(s) of monetary or material Support: currently under review

Intervention

Outcome measures

Primary outcome

- Wexner-score

- Fecal Incontinence Quality of Life score (FIQL)

Secondary outcome

- EORTC Colorectal Quality of Life Questionnaire QLQ-CR38

- defecation diary

- LARS-score

- preoperative radiotherapy or radiochemotherapy

- perioperative parameters

- level of anastomosis

- morbidity and mortality related to surgery

Study description

Background summary

It is widely accepted that 90% of patients undergoing sphincter-preserving rectal surgery, will subsequently have a change in bowel habit, ranging from increased bowel frequency to fecal incontinence or evacuatory dysfunction. A two-armed randomized controlled trial will be conducted in patients who underwent sphincter-preserving rectal cancer surgery. This trial aimed to evaluate the incremental effect of PFR on the functional outcomes in patients after sphincter-preserving rectal cancer surgery. Patients will be randomized for standardized PFR or regular treatment. The study will be a multicenter trial in several tertiary referral centers and teaching hospitals. 56 patients will be included in each arm of the protocol. The total number of 112 patients will be included during an 18 month period and a minimal follow-up time of 1 year is necessary.

Study objective

Improving functional outcomes in rectal cancer surgery by a pelvic floor rehabilitation program.

Study design

- Preoperative questionnaires

- Postoperative questionnaires and start of PFR 3 months after surgery (T0)

- 12 therapy sessions during 3 months

- Questionnaires after 3 months of PFR (T1)

- Questionnaires 12 months after start PFR (T2)

Intervention

Pelvic floor rehabilitation after low anterior resection for rectal cancer, including pelvic floor muscle training, biofeedback, electrostimulation and rectal balloon training.

Contacts

Public
B.R. Klarenbeek
Bakkersteeg 11
Leiden 2311 RH
The Netherlands
+31 (0)6 41254152
Scientific
B.R. Klarenbeek
Bakkersteeg 11
Leiden 2311 RH
The Netherlands
+31 (0)6 41254152

Eligibility criteria

Inclusion criteria

- Patients undergoing a low anterior resection for rectal cancer.

- Age over 18 years.

Exclusion criteria

- No informed consent.

- Certain comorbidities: proctitis, colitis ulcerosa, Crohn's disease

- Necessity for resection beyond TME, ie T4 tumor.

- Previous course of pelvis radiotherapie, for other reasons then the current rectal carcinoma.

- Pelvic floor rehabilitation therapy in the last six months prior to rectal resection.

- Life expectancy less than 1 year.

- Mental or physical condition, that compromises the feasibility of the intervention.

- Not mastering the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	112
Type:	Anticipated

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	NL5368
NTR-old	NTR5469
Other	: 80-84300-98-72021

Study results

Summary results
Wilhelmina S Visser, Wouter W te Riele, Djamila Boerma, Bert van Ramshorst, Henderik L van Westreenen. Pelvic Floor Rehabilitation to Improve Functional Outcome After a Low Anterior Resection: A Systematic Review. Annals of Coloproctology 2014; 30(3):109-114.