Pelvic Floor Rehabilitation to improve functional Outcome and quality of life after surgery for Rectal CancEr: a randomized controlled trial (FORCE TRIAL)

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Primary Objective: To evaluate the effect of PFR compared to standard treatment on FI in patients after LAR, by measuring the Wexner-score and the Fecal Incontinence Quality of Life Score (FIQL-score).Secondary objective:To analyse the cost...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON47338

Source
ToetsingOnline

Brief title
FORCE TRIAL

Condition

- Gastrointestinal motility and defaecation conditions
- Muscle disorders
- Gastrointestinal therapeutic procedures

Synonym
fecal incontinence, urgency and frequency

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Novuqare, Nederland (producent van MAPLE probes),ZonMw (Ministerie van OC&W en NWO)

Intervention

Keyword: cost effectiveness, functional outcome and quality of life, pelvic floor rehabilitation, rectal cancer

Outcome measures

Primary outcome

Primary outcome measures are the Wexner Score and the Fecal Incontinence

Quality of Life score (FIQL) . The measurement by the Wexner Score and the FIQL

after the interventie (M3) will be the primary outcome. The follow-up

measurement (M4) is to observe the long term effect of the intervention.

(look 8.1 Study endpoints page 26)

Secondary outcome

The economic effects of full implementation of PFR compared to standard

treatment in treating FI in patients after LAR, will be determined by a cost

effectiveness analysis.

(look 8.1 Study endpoints page 26)

Study description

Background summary

Up to 90% of the patients develop anorectal dysfunctions after a low anterior resection (LAR), which is a sphincter saving technique (3). Especially fecal incontinence has major (1-3) impact on physical, psychological, social and emotional functioning of the patient. (4,5). Alongside, fecal incontinence has a substantial impact on the National Healthcare budget with over ¤2000 spent per patient per year (6). There is no standardized treatment protocol to help these patients. The standard treatment is focused on symptom relief, consisting of pharmacotherapy like bulking agents and/or anti-diarrhetics. Another treatment is Pelvic floor rehabilitation, one of the most important treatments for fecal incontinence in general, with success rates of 50-80% (7-9).
The FORCE-trial randomizes rectal cancer patients after sphincter saving rectal resection for either a standardized pelvic floor rehabilitation program or standard treatment, in order to reduce complaints and costs of fecal incontinence.

(look Introduction and rationale page 13)

Study objective

Primary Objective:
To evaluate the effect of PFR compared to standard treatment on FI in patients after LAR, by measuring the Wexner-score and the Fecal Incontinence Quality of Life Score (FIQL-score).

Secondary objective:
To analyse the cost effectiveness of full implementation of PFR compared to standard treatment in treating and preventing FI in patients after LAR.

(look Objectives page 14)

Study design

The FORCE-trial is a multicenter, two-armed, randomized, clinical trial.

Rectal cancer patients (>18 year) indicated for sphincter saving rectal resection (LAR) are eligible for inclusion in this trial. After recovery of surgery, patients are randomized for either a standardized pelvic floor rehabilitation (PFR) program or standard treatment. The study flow-chart is depicted in figure 1. Patients will be recruited in the participating hospitals. Three months after LAR or 6 weeks after stoma closure randomization will take place and patients will be divided in two groups: intervention group and

control group. The intervention group wil be treated by selected and registered pelvic floor specialized physiotherapists and the treatment consists of pelvic floor rehabilitation. The controlegroep will be treated with the standard treatment (bulking agents and/or diarhoe inhibitors)
Measuring will take place by questionnaires, Wexner score en FIQL score , derived from the DeFeC score and patients will also be asked to undergo anorectal function tests. This will take place before surgery (M1), 3 months after LAR or 6 weeks after stoma closure (M2), after intervention (M3) and also after one year to measure the long term effect of the treatment (M4).
The sample size of this study is 168 (84 per arm)

(look Study design page 15, Study duration page 16 and Sample size calculation page 19).

Intervention

The treatment of the patients of the intervention group consists of 12 treatment sessions by a registered pelvic floor specialized physiotherapist during 12 weeks. These pelvicfloor specialized physiotherapist are selected based on educationlevel and registration (KNGF-NVFB register), location (around the four participating hospitals) and experience with treatment equipment (MAPLe Novuqare).
This treatment is protocolled and consists of four modalities:
1) Pelvic floor muscle training to improve maximum force, lengthening of contraction period and better timing and coordination of contraction.*
2) Biofeedback is a behavior therapy to give the patient insight in the contraction and relaxation of the pelvic floor muscles by using an anal electromyographic probe.*
3) Electrostimulation can improve the effectiveness of the contractionstrength of the pelvic floor muscles and anal sphincter, using the same anal electromyographic probe as for biofeedback.*
4) Rectal balloon training to simulate urgency to defecate. By this method the retaining of stool and capacity of the rectum can be trained.

(look Chapter 5 Treatment page 20-23)

Study burden and risks

The risk of the current study is negligible.
The patients of intervention group need a good motivation, cooperation to follow the complete trajectory of treatment of 3 months and there has to be a good willingness and self-discipline to exercise in home situation every day. So the burden of this treatment is medium.
The results of this study may substantially improve care for patients with faecal incontinence after a LAR for rectal cancer. When there will be evidence that PFR is a good treatment for patients with fecal incontinence after rectal

cancer surgery the after treatment will change exceptional. BFR will be a treatment belonging to the standard treatment of these functional problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Patients underwent low anterior resection for rectal carcinoma
- Age * 18 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Comorbidity in history like proctitis, colitis ulcerosa, Crohn disease.
- Locally advanced (T4) tumors indicated for extensive resection (beyond TME)
- Previous history of pelvic radiation (other than rectal cancer)
- Pelvic Floor Rehabilitation during last 6 months
- Life expectancy < one year
- Mentally or physically not able to undergo the intervention
- No informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-10-2017
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2017
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-05-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-10-2018
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Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-10-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-12-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-05-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-09-2019
Application type:	Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL59799.091.16