

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29552

### Source

NTR

### Brief title

FORCE II

### Health condition

Rectal cancer; pelvic floor rehabilitation (PFR); fecal incontinence, Low Anterior Resection Syndrome (LARS), TAMIS, transanal TME (taTME).

## 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. The new approach for low rectal tumors, transanal total mesorectal excision (taTME), is thought to cause even more incontinence. A two-armed randomized controlled trial will be conducted in patients who underwent taTME. This trial aimed to evaluate the incremental effect of PFR on the functional outcomes in patients after taTME. 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 after transanal TME by a pelvic floor rehabilitation program.

### **Study design**

- 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 taTME for rectal cancer, including pelvic floor muscle training, biofeedback, electrostimulation and rectal balloon training.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

- Patients undergoing a taTME 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.
- No master of the Dutch language.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### 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	NL5369
NTR-old	NTR5470
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.