

# Prehabilitation for bowel cancer patients undergoing surgery to improve fitness and reduce complications

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21887

### Source

NTR

### Brief title

PREHAB

### Health condition

Colorectal carcinoma

## Sponsors and support

**Primary sponsor:** Máxima MC

**Source(s) of monetary or material Support:** Máxima MC

## Intervention

## Outcome measures

### Primary outcome

The first primary outcome is postoperative complications, as scored using the Comprehensive Complication Index score as a combined outcome measure of morbidity and mortality. The second primary/confirmatory outcome is the patients' functional capacity, as measured by

the six-minute walk test (6MWT).

## Secondary outcome

Secondary outcomes will include indirect 1 repetition measures (1-RM) and cardiopulmonary exercise testing (CPET), Health-related quality of life (HRQL), Sit-to-Stand test, Fried Frailty Score, hand grip strength, body composition, stair climb test, Physical activity level measured through an activity questionnaire, depression and anxiety assessed by GAD-7 and PHQ-9, nutritional status, compliance, length of hospital stay, and costs.

# Study description

## Background summary

### Background

Colorectal cancer (CRC) is the second most prevalent type of cancer in the World. The only way to cure is surgical removal of the tumor. However, postoperative complications occur in up to 50% of patients and are associated with a higher mortality- and return of cancer rate and increased hospital costs. The number and severity of complications is closely related to preoperative functional capacity, nutritional state and smoking behavior. Traditional approaches have targeted the postoperative period for rehabilitation and lifestyle changes. However, recent evidence shows that the preoperative period might be the optimal time frame for intervention. This study will determine the exact effect of prehabilitation on patients' functional capacity and postoperative complications.

### Methods/design

This international multicenter, prospective, randomized controlled trial will include 714 patients undergoing colorectal surgery for cancer. Patients will be allocated to an intervention group, receiving four weeks of prehabilitation or the control group receiving no prehabilitation. Both groups perioperative care following ERAS guidelines. The primary endpoints are functional capacity and postoperative status determined by the Comprehensive Complication Index (CCI). Secondary outcomes include health related quality of life (HRQoL), Patient Reported Outcome Measurements (PROMs), length of hospital stay and a cost-effectiveness analysis.

### Discussion

This is the first international multicenter study focusing on multimodal prehabilitation for patients undergoing colorectal surgery for cancer. Prehabilitation is expected to increase

functional capacity and to lower postoperative complications. Consequently, this may result in increased survival and improved HRQoL.

### **Study objective**

Multimodal prehabilitation decreases postoperative complications and improves functional capacity pre- and postoperatively for patients undergoing colorectal surgery for cancer.

### **Study design**

Baseline (diagnosis), Preoperative (4 weeks after diagnosis), 4 weeks postoperative, 8 weeks postoperative, 1 year postoperative

### **Intervention**

1. Patient triage medical conditions
2. Exercise program
3. Nutritional supplements
4. Smoke cessation
5. Psychological coping

## **Contacts**

### **Public**

P.O. Box 7777

Gerrit Slooter  
Veldhoven 5500 MB  
The Netherlands  
+3140 - 8885320

### **Scientific**

P.O. Box 7777

Gerrit Slooter  
Veldhoven 5500 MB  
The Netherlands  
+3140 - 8885320

## Eligibility criteria

### Inclusion criteria

Adult patients undergoing elective colorectal surgery for cancer.

### Exclusion criteria

- metastatic disease known preoperatively,
- paralytic or immobilized patients (not capable to perform exercise or 6MWT),
- premorbid conditions or orthopedic impairments that contraindicate exercise (to be assessed by sport physician involved in and during cardiopulmonary exercise testing),
- cognitive disabilities,
- chronic renal failure (dialysis or creatinine > 250 µmol/l)
- ASA score 4 or higher,
- illiteracy (disability to read and understand Dutch),
- planned abdominoperineal resection (inability to perform postoperative tests),
- second primary tumour other than colorectal carcinoma simultaneously diagnosed,
- not able to delay surgery for four weeks due to for example clinical signs of obstruction or short-course neoadjuvant radiotherapy, directly followed by surgery.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2017
Enrollment:	715

Type: Anticipated

## IPD sharing statement

**Plan to share IPD:** No

## Ethics review

Positive opinion

Date: 01-08-2016

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 50479

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL5784
NTR-old	NTR5947
CCMO	NL58281.015.16
OMON	NL-OMON50479

## Study results

### Summary results

Kim DJ, Mayo NE, Carli F, Montgomery DL and Zavorsky GS; Responsive Measures to Prehabilitation in Patients undergoing bowel resection surgery. Toboku J. Exp. Med. 2009, 217, 109-115.<br>

Carli F, Charlebois P, Stein B, Feldman L, Zavorsky G, Kim DJ, Scott S, Mayo NE. Randomized clinical trial of prehabilitation in colorectal surgery. BJS 2010; 97: 1187-1197.<br>  
JJ Dronkers, H Lamberts, IMMD Reutelingsperger, RH Naber, CM Dronkers-Landman, A Veldman and NLU van Meeteren; Preoperative therapeutic programme for elderly patients scheduled for elective abdominal oncological surgery: a randomized controlled pilot study. Clinical Rehabilitation 2010; 24: 614-622.<br>  
GILLIS, C., LI, C., LEE, L., AWASTHI, R., AUGUSTIN, B., GAMSA, A., LIBERMAN, A.S., STEIN, B., CHARLEBOIS, P., FELDMAN, L.S. and CARLI, F., 2014. Prehabilitation versus rehabilitation: a randomized control trial in patients undergoing colorectal resection for cancer. Anesthesiology, 121(5), pp. 937-947