

# Prehabilitation in colorectal cancer patients scheduled for elective colorectal resection

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal neoplasms malignant and unspecified
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44777

### Source

ToetsingOnline

### Brief title

Prehabilitation in colorectal cancer patients

### Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

### Synonym

Colorectal cancer, large bowel and rectal cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medisch Spectrum Twente

**Source(s) of monetary or material Support:** Zorgverzekering of via stichting wetenschappelijk onderzoek chirurgen Enschede

## Intervention

**Keyword:** Anaerobic threshold, CardioPulmonary Exercise Testing, Colorectal cancer, Prehabilitation

## Outcome measures

### Primary outcome

The primary endpoint of this research are the postoperative complications within 30 days after elective colorectal surgery. We expect a decrease in postoperative complications from 73 percent to 33 percent in the prehabilitation group.

### Secondary outcome

The secondary objectives are to observe what happens with the anaerobic threshold in the intervention group and the control group. Also the effect of the prehabilitation program on length of stay in hospital will be observed. The value of a limited geriatric assessment in this patients group will also be investigated.

## Study description

### Background summary

Abdominal surgical interventions in elderly patients with colorectal cancer are increasing. According to the Dutch Surgical Colorectal Audit, 33 percent of the colorectal patients have one or more postoperative complications after elective colon surgery. The elderly in particular are prone to postoperative complications. Studies show that an anaerobic threshold below 11 ml/kg/min is a good predictor of postoperative complications. Patients with an anaerobic threshold below 11 ml/kg/min are considered high-risk. Current studies show that high-risk patients who were placed on an exercise program before elective surgery, improve their cardiopulmonary capacity. Based on an interim analysis, our hypothesis is that preoperative training of high-risk patients with colorectal cancer reduces the postoperative complication rate from 73 to 33

percent.

## **Study objective**

The primary objective of the research is to measure the effect of a 3 week prehabilitation program on the postoperative complications in patients with an anaerobic threshold of  $<11$  ml/kg/min who will undergo elective colorectal surgery for colorectal cancer.

The secondary objectives are to observe what happens with the anaerobic threshold and inspiratory muscle strength in the intervention group and the control group. Also the effect of the prehabilitation program on the length of stay in hospital will be observed.

## **Study design**

This study is a multicenter prospective randomized controlled trial. The interventions, prehabilitation versus usual care, are randomly assigned to the patients. The effect of prehabilitation versus no prehabilitation will be compared. This trial will run from fall 2013 until all patients are included, this will probably be in December 2018. The study will take place in Medisch Spectrum Twente in Enschede and ZGT in Almelo.

## **Intervention**

27 patients will receive 3 weeks of physiotherapy before surgery. The physiotherapy consists of one hour cardiopulmonary training on an exercise bicycle, three times a week. The control group will receive regular health care.

## **Study burden and risks**

Only patients in the intervention group will in all likelihood benefit from the study. Those in the control group will not benefit. The risk for adverse events in this study is negligible. The patients will have to invest some extra time during this study. They have to perform a cardiopulmonary exercise test twice, which will take 1,5 hour. The intervention group will have to participate in the physiotherapy training for 9 hours.

## **Contacts**

### **Public**

Medisch Spectrum Twente

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

- \* 60 years
- Colon cancer or rectal cancer
- Undergoing elective colorectal surgery
- Having a life expectancy of more then 6 months
- Has given informed consent to participate in the study
- Metabolic equivalent score of \*7 on the Veterans Specific Activity Questionnaire
- Anaerobic threshold < 11 ml/kg/min after the first CPET
- Able to perform a cardiopulmonary exercise test
- Will be operated at Medisch Spectrum Twente at Enschede
- Will be treated at a private physiotherapy practice in the catchment of the Medisch Spectrum Twente Hospital
- Patients with grade I, II or III dysplasia in a colorectal polyp requiring colorectal resection

### Exclusion criteria

- Anaerobic threshold \* 11 ml/kg/min after the first CPET
- Not capable to perform a cardiopulmonary exercise test
- Undergoing emergency colorectal surgery

- Meeting the absolute and/or relative exclusion criteria from the CPET protocol used in Medisch Spectrum Twente.

## Study design

### Design

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

**Primary purpose:** Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2014
Enrollment:	54
Type:	Actual

## Ethics review

Approved WMO	
Date:	03-09-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	19-11-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	08-05-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	

Date:	06-01-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	02-07-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	07-07-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	07-03-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	21-09-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

## Study registrations

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

No registrations found.

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

ID: 26329  
Source: NTR  
Title:

### In other registers

Register	ID
CCMO	NL45001.044.13
Other	trialregister NTR 4032

**Register**

OMON

**ID**

NL-OMON26329