

# Identification of baseline functional capacity of patients undergoing surgery for colorectal cancer.

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To investigate patients' preoperative physical fitness, deconditioning due to hospitalisation with patients undergoing colorectal surgery for colorectal cancer. This study will serve as a control group for the prehabilitation study which will...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON44094

### Source

ToetsingOnline

### Brief title

Baseline functional capacity bowel cancer patients.

### Condition

- Gastrointestinal conditions NEC

### Synonym

colorectal cancer, colorectal neoplasms

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Maxima Medisch Centrum

**Source(s) of monetary or material Support:** ziekenhuis MMC

## Intervention

**Keyword:** Colorectal cancer, Functional capacity, Surgery

## Outcome measures

### Primary outcome

Cardiopulmonary condition: VO2max test, steep ramp test, 6-min walk test.

Muscle strength: 1-RM test.

### Secondary outcome

Quality of life questionnaires EORTC 29 and 30, SF-36, PHQ-9, GAD-7.

Nutrition status: food diary, NRS2002, PG-SGA.

Muscle composition: CT scan preoperatively (standard care)

Physical activity: accelerometer, CHAMPS score.

## Study description

### Background summary

Colorectal cancer (CRC) is the second most prevalent type of cancer with an expected incidence of 15.000 patients in 2015 in the Netherlands. Surgery is always an essential first step in treatment of CRC. Postoperative complications occur in up to 50% of patients and are associated with higher return of cancer and substantial increase in hospital costs. If patients survive they have a substantial decrease in physical fitness resulting in a lower Health Related Quality of Life (HRQoL). Moreover, after operation many patients may need to undergo further treatment like chemotherapy. This is more difficult if physical fitness is lowered.

The number and the severity of complications is closely related to preoperative physical fitness, 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 is the optimal time frame for intervention. This time frame between diagnosis and operation is restricted to 4-5 weeks. From a physiological point of view and based on limited practical experience, it seems feasible to achieve clinical relevant effects during this time frame. Only, if robust innovative interventions of feeding and training are combined.

## **Study objective**

To investigate patients' preoperative physical fitness, deconditioning due to hospitalisation with patients undergoing colorectal surgery for colorectal cancer. This study will serve as a control group for the prehabilitation study which will start in the end of 2016. In 2016, patients will receive individualized exercise training, nutritional support and a smoke cessation program.

This control group will tell if a preoperative intervention could lead to improved functional capacity preoperatively, compared to patients without a preoperative intervention. Baseline information is needed to develop and implement the right intervention for further research.

Research questions:

- 1) What is the functional capacity of patients undergoing colorectal surgery for colorectal cancer?
- 2) Is the preoperative physical status related to postoperative complications?
- 3) Could patients' functional capacity be improved preoperatively?

## **Study design**

Patients will be asked for participation when diagnosis of colorectal cancer is performed. Four quality of life questionnaires will be performed. Moreover, patients' physical status is measured using a VO2 max, steep ramp test, 1-RM test and six minute walk test.

## **Study burden and risks**

All possible risks will be documented and reported to the METC.

Possible risks:

The VO2max test carries a minor risk on cardiac events, although a negligible risk.

## Contacts

### Public

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NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All adult patients undergoing elective colorectal surgery for colorectal cancer with primary anastomosis.

### Exclusion criteria

Multi organ resections, intraoperative radiotherapy, neoadjuvant therapy, inability to perform exercise.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 12-07-2016

Enrollment: 50

Type: Actual

## Ethics review

Approved WMO

Date: 18-03-2016

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

Approved WMO

Date: 06-03-2017

Application type: Amendment

Review commission: METC Maxima Medisch Centrum (Veldhoven)

## 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	NL54547.015.15