

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21887

Bron

NTR

Verkorte titel

PREHAB

Aandoening

Colorectal carcinoma

Ondersteuning

Primaire sponsor: Máxima MC

Overige ondersteuning: Máxima MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Multimodal prehabilitation decreases postoperative complications and improves functional

capacity pre- and postoperatively for patients undergoing colorectal surgery for cancer.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adult patients undergoing elective colorectal surgery for cancer.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-06-2017
Aantal proefpersonen:	715
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 01-08-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50479

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.

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.

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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.

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CHARLEBOIS, P., FELDMAN, L.S. and CARLI, F., 2014. Prehabilitation versus rehabilitation: a
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