

Prehabilitation in colorectal cancer patients scheduled for elective colorectal resection

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26329

Bron

Nationaal Trial Register

Aandoening

Colorectal cancer, low anaerobic threshold

Colorectaal kanker, lage anaerobe drempel

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente, surgery department.

Overige ondersteuning: fonds = verrichter = sponsor.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative complications (pulmonary, renal, gastrointestinal, infective, cardiovascular,

neurological, haematology, pain, wound) within 30 days after surgery in group A and B.

Toelichting onderzoek

Achtergrond van het onderzoek

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. Our hypothesis is that preoperative training of high-risk patients with colorectal cancer reduces the postoperative complications from 50 to 20 percent.

Doel van het onderzoek

Since the overall morbidity rate is 33 percent we expect the high-risk group (with an anaerobic threshold < 11 ml/kg/min) to have a morbidity rate of 50 percent. The effect of prehabilitation is expected to decrease the morbidity rate to 20 percent in this specific group. We hypothesize that prehabilitation reduces the amount of postoperative complications from 50 percent to 20 percent in patients with a low cardiorespiratory reserve undergoing elective colorectal surgery for colorectal cancer.

Onderzoeksopzet

Complications on the 7th postoperative day and the 30th postoperative day.

Onderzoeksproduct en/of interventie

The primary endpoint of this study is the number of postoperative complications within 30 days after elective colorectal surgery.

In this study, 42 patients will receive 4 weeks of physiotherapy before surgery. The physiotherapy consists of one hour, high intensity, cardiopulmonary training combined with periphery muscle training, three times a week. The patients will train on Monday, Wednesday and Friday. The training contains cardio-training and muscle strength training (arm and legs) and will be adjusted to the cardiopulmonary reserve of the individual patient, based upon the results of the cardiopulmonary exercise test and the spirometry. The training will be performed under the guidance of a physiotherapist in a private physiotherapy practice in the

catchment of the Medisch Spectrum Twente Hospital. Also the patient fulfill home exercises, like walking or cycling and climbing up a stairs, for two times a week for at least 30 minutes at a time, unsupervised, on a moderate level of intensity.

The control group of 42 patients will receive regular health care, without physiotherapy or home exercises.

All patients perform a CPET twice. One CPET at the beginning of the study (before the intervention) and one CPET after 4 weeks. The anaerobic threshold will be measured in the intervention group (with physiotherapy) and in the control group (without physiotherapy). Both groups will undergo colorectal surgery. The postoperative complications will be recorded within 30 days after surgery by using the Clavien-Dindo classification.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Older than 18 years;
- Colon or rectal cancer;
- Undergoing elective colorectal surgery;
- Having a life expectancy of more then 6 months;
- Has given consent to participate in the study;
- Metabolic equivalent score
- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Anaerobic threshold \geq 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. These criteria are based on the criteria from the American Thoracic Society and American College of Chest Physicians Statement on CPET.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44777
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3843
NTR-old	NTR4032
CCMO	NL45001.044.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44777

Resultaten

Samenvatting resultaten

N/A