Prehabilitation in colorectal cancer patients scheduled for elective colorectal resection

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26329

Source
Nationaal Trial Register

Health condition

Colorectal cancer, low anaerobic threshold

Colorectaal kanker, lage anaerobe drempel

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, surgery department.
Source(s) of monetary or material Support: fonds = verrichter = sponsor.

Intervention

Outcome measures

Primary outcome

Postoperative complications (pulmonary, renal, gastrointestinal, infective, cardiovascular, neurological, haematology, pain, wound) within 30 days after surgery in group A and B.

Secondary outcome

-Improvement of AT after the prehabilitation program in the intervention group;

-Natural decline of the cardiopulmonary fitness in the control group by measuring the anaerobic threshold after diagnosis of colorectal cancer and 4 weeks later;

-Length of stay in hospital after surgery;

-Postoperative complications within 30 days after surgery in patients with an anaerobic threshold ¡Ý 11 ml/kg/min after the first CPET;

-Improvement of the inspiratory muscle strength after cardio-fitness training.

Study description

Background summary

Abdominal surgical interventions in elderly patients with colorectal cancer are increasing. According to the Dutch Surgcial 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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

-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.

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. These criteria are based on the criteria from the American Thoracic Society and American College of Chest Physicians Statement on CPET.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	84
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44777
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A