Multimodal prehabilitation program in colorectal cancer patients to improve functional capacity and reduce postoperative complications.

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To design, implement and test a multimodal prehabilitation program in order to lower the complication rate and improve recovery rate for patients undergoing colorectal surgery for colorectal cancer by enhancing functional capacity (cardiopulmonary...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON50479

Source
ToetsingOnline

Brief title
Prehabilitation to improve colorectal care (PREHAB)

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, colorectal neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: KWF,Subsidie KWF

Intervention

Keyword: Colorectal cancer, Functional capacity, Postoperative complications, Prehabilitation

Outcome measures

Primary outcome

Postoperative complications determined by the comprehensive complication index

(CCI).

Functional capacity measured by the 6MWT.

Secondary outcome

VO2-max test, sit-to-stand test, hand-grip strength, stair climb test.

Health related quality of life determined by the SF-36, EORTC QLQCR29 and EORTC

QLQC30.

Activity questionnaire, GAD-7, PHQ-9, fried frailty score, food diary.

Activity (accelerometer), anthropometry (body composition).

Study compliance.

Length of hospital stay, 30 day morbidity and mortality.

Cost-effectiveness analysis.

Study description

Background summary

Colorectal cancer is the second most prevalent type of cancer in the world with over 800.000 patients diagnosed yearly. Colorectal surgery is the most

essential step in curative treatment of this disease. In up to 50% of patients undergoing colorectal surgery complications occur postoperative. This leads to an increase of hospitalization length, an increase in health care costs to almost 200%, a higher morbidity and mortality rate and a lower health related quality of life.
It is known that the number and the seriousness of complications is highly correlated to patients' preoperative health status. This health status is highly correlated tot nutritional state, smoking behaviour and functional excercise capacity. Colorectal cancer patients often have a poor lifestyle en often develop problems with nutritional state, which may aggravate deconditioning and muscle wasting. This implies that especially in this group of patients there is much room for improvement and so seems appropriate to test if a prehabilitation program leads to a decrease of complications.

Study objective

To design, implement and test a multimodal prehabilitation program in order to lower the complication rate and improve recovery rate for patients undergoing colorectal surgery for colorectal cancer by enhancing functional capacity (cardiopulmonary capacity, muscle strength, nutritional state and smoking behaviour) preoperatively.

Study design

In this international multicenter, prospective, randomized controlled trail patients will be allocated an intervention group, receiving 4 weeks prehabilitation or the control group receiving standard care. Both groups obtain perioperative care following ERAS guidelines.

Intervention

Prehabilitation group will receive supervised exercise training by a physiotherapist/kinesiologist, three times a week during 4 weeks. Additional protein supplements (daily after training and before sleep) and (multi)vitamins will be supplied. Every patient in the intervention group will receive an intake with a trained member of the research team and when indicated, a referral to the psychologist. A dietician provides dietary advice and advice on adequate protein intake to improve nutritional status.

Study burden and risks

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

De VO2-max test has a very small risk of cardiologic complications. By measurement of cardiopulmonary capacity of patients one can rule on condition progress in more detail. Also, it gives additional information about potential

present heart and/or lung disease and overall cardiopulmonary capacity. This gives a better insight in surgical risk and it makes it possible to lower this surgical risk by adjustments preoperatively.

Potential benefits are improvement in cardiopulmonary fitness, muscle strength and nutritional status. Also improvement in coping with disease and related anxiety and stress. These elements might result in an improved postoperative recovery and less postoperative complications. This advantage is for all patients participating in the study since it is not part of normal care.

Contacts

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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

Exclusion criteria

Metastatic disease known preoperatively
Chronic renal failure (dialysis or creatinine >250 micromol)
ASA score of 4 or higher
Cognitive disabilities
Inability to perform exercise
Illiteracy (ability to read and understand Dutch written language)
Second primary tumour other than colorectal carcinoma simultaneously diagnosed
Not able to delay surgery for 4 weeks, due to for example clinical signs of obstruction or short-course neo-adjuvant radiotherapy directly followed by surgery

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-07-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	24-08-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Not approved Date:	13-04-2018
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-11-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-12-2019
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-03-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	14-09-2020
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

ID: 21887
Source: NTR
Title:

In other registers

Register	ID
Other	NL5784
CCMO	NL58281.015.16
OMON	NL-OMON21887