A multimodal prehabilitation and rehabilitation program for frail older colorectal cancer patients

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Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON52663

Source
ToetsingOnline

Brief title
Better Be on top (BEBOP)

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
'Colorectal cancer' 'Colon or rectal tumour'

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Via stichting Team Westland

Intervention

Keyword: Colorectal cancer, elderly, frail, prehabilitation

Outcome measures

Primary outcome

Baseline characteristics, information about the prehabilitation and rehabilitation program will be prospectively collected from the medical records. Patients demographics, tumour and treatment characteristics and postoperative complications, will be prospectively collected through the nationwide obligatory data collection of Dutch ColoRectal Audit (DCRA). Information about one year mortality, functional status and quality of live outcomes, are obtained through the Triage of Elderly Needing Treatment (TENT) study.

Secondary outcome

Not applicable

Study description

Background summary

As the incidence of colorectal cancer (CRC) is increasing with age and several surgical developments have been made the past few years, the number of older patients receiving surgical treatment is increasing. However, the impact of surgery should not be underestimated in the older CRC patients. Especially the frail older CRC patients have higher mortality and postoperative complication rates in comparison to the non-frail patients. Identifying and modifying vulnerabilities before and after surgery may increase the capacity and decrease the impact of surgery. Evidence of prehabilitation with or without the combination of rehabilitation is limited and inconsistent due to studies with small sample sizes and the inclusion of non-frail patients. This means that a large cohort study is needed to establish the effect of prehabilitation and

rehabilitation in frail older CRC patients.

Study objective

The aim is to investigate the effect of a multimodal prehabilitation and rehabilitation program in frail patients of 70 years or older, undergoing elective surgery for non-metastatic CRC on

1. One-year mortality
2. Postoperative complications, surgical and non-surgical complications
3. Functional capacity, quality of life (QoL)
4. Physical performance, nutritional status and cognitive status

Study design

A multicentre prospective experimental cohort study implemented by a stepped wedge design.

Intervention

Patients are included in the control group or in the prehabilitation and rehabilitation (intervention) group according to a stepped wedge design. In addition to standard care, all patients in the intervention group will preoperatively undergo a multimodal program, including a four to six weeks exercise program including strength and endurance training, diet advice and nutritional support, psychosocial support, smoking cessation and additional medical optimization, e.g. iron infusion for iron deficiency anaemia. Postoperatively, patients will start postoperative rehabilitation, including minimally four weeks exercise program and nutritional monitoring.

Study burden and risks

The prehabilitation and rehabilitation program might be demanding, because of the exercise program and the fact that patients need to visit the hospital more frequently. Therefore patients might be at risk for overuse complaints, as fatigue or muscle or joint pain.

The prehabilitation period consists of at least two appointments at the clinical physiotherapist (30-45min), an appointment at the dietician (45min), a nutritional evaluation by telephone (15 min), an exercise program of 4-6 weeks (2-3x p week) and when necessary, patients may receive psychologic support, smoking cessation and iron infusion. If iron infusion is indicated, it will be performed under supervision and a patient will stay at least 30 minutes in the hospital after the infusion has stopped to monitor potential allergic reaction. An allergic reaction is rare (0.01-0.1%).

In the rehabilitation period, patients need to perform an exercise program of at least 4 weeks and have nutritional evaluation by telephone. In the follow-up patients need to perform physical and cognitive tests at 3, 6 and 12 months and if indicated patients will be monitored by the dietician by telephone or by hospital visits. As part of the TENT study patients will be contacted to provide information about QoL, ADL and IADL at 6 and 12 months.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- diagnosed with colorectal cancer at the age >= 70 years
- no metastatic disease
- planned for elective surgery
- positive geriatric screening based on the G8 or 6CIT

Exclusion criteria

- potential need for surgery in semi-acute of urgent setting due to medical reasons, e.g. obstructive tumour complaints, faecal incontinence etc.
- eventually no need for surgery due to complete tumour remission after chemo-radiation in rectal cancer patients
- not willing to provide informed consent for the current study
- not willing to provide informed consent for the TENT study
- not able to provide informed consent
- not able to perform an exercise program; for instance wheelchair-dependent patients or paraplegic patients
- patients in whom exercise program is contra-indicated due to severe cardiopulmonary problems, diagnosed by a cardiologist and/or pulmonologist (for example COPD gold IV, unstable coronary artery disease, heart failure or poorly controlled arrhythmias).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-02-2021
Enrollment:	490
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2020

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	11-11-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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: 25416
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL72163.058.19
Other	NL8107