Taking control of prehabilitation in older patients with colorectal carcinoma

Published: 29-07-2021
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Investigate whether continuous monitoring of physical activity with an activity tracker leads to an improvement in preoperative endurance in elderly people with colorectal cancer, compared to a standard preoperative route with prehabilitation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON50910

Source
ToetsingOnline

Brief title
Taking control of prehabilitation

Condition

- Gastrointestinal therapeutic procedures

Synonym
colonrectal oncology, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St Antonius onderzoeksfonds

Intervention

Keyword: colorectal cancer, older patients, prehabilitation, surgery

Outcome measures

Primary outcome

Primary endpoint is an improvement of >=50 meters on the 6 minute walk test on the day before surgery, compared to the start of the prehabilitation program.

Secondary outcome

Secondary endpoints are preoperative muscle strength (hand grip strength and Five Times Sit to Stand (FTSTS) test) and quality of life, serious postoperative complications (Clavien Dindo grade >=3) within 30 days, quality of life and functional limitations at 3 months.

Study description

Background summary

Preoperative physical inactivity is a major cause of loss of function after abdominal surgery. The preoperative period can be used to improve the muscle strength and endurance of patients (prehabilitation). Compliance plays an important role in successful prehabilitation. This study investigates the effect of an activity tracker on preoperative endurance in elderly people with colorectal cancer.

Study objective

Investigate whether continuous monitoring of physical activity with an activity tracker leads to an improvement in preoperative endurance in elderly people with colorectal cancer, compared to a standard preoperative route with prehabilitation.

Study design

Randomized controlled singel center trial

Study burden and risks

Control group: Completing two additional questionnaires (EORTC QLQ-C30 and WHODAS-2.0 12-item, appendix 1 and 2) at the start of the study, upon admission before surgery and after 3 months, performing a 6-minute walking test, grip strength and FTSTS (total ± 20 minutes) at study start and before surgery, standard prehabilitation program (Appendix 3). Intervention group: Completing the additional questionnaires at the start of the study, at admission to hospital and after 3 months, performing a 6 minute walk test, squeeze force and FTSTS (in total ± 20 minutes) at the start of the study and before the operation, wearing an activity tracker (Fitbit) during the day, digital sharing of anonymous activity tracking data

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1 Koekoekslaan 1
Nieuwegein 3430 EM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1 Koekoekslaan 1
Nieuwegein 3430 EM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Elective surgery for colorectal cancer
Age 70 or above

Exclusion criteria

Double tumor
Metastatic disease
Neoadjuvant chemo/radiotherapy

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2021
Enrollment:	104
Type:	Actual

Medical products/devices used

Generic name:	Fitbit Charge 4
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-07-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-08-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 20870
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77624.100.21