Evaluation of a home-based prehabilitation program for high-risk patients undergoing major elective abdominal surgery: a one-group pre-test post-test pilot study.

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48744

Source
ToetsingOnline

Brief title
Home-based prehabilitation in major abdominal surgery

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign
- Head and neck therapeutic procedures

Synonym
Colorectal cancer, hepatic cancer, pancreatic cancer

Health condition

Tumoren in darm, lever of pancreas waarvoor resectie gepland is

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Oncology, Prehabilitation, Risk stratification, Surgery

Outcome measures

Primary outcome

The main study parameter is the feasibility (adherence/compliance, adverse events, and patient appreciation) of a four-week home-based prehabilitation program in individual high-risk patients scheduled for elective colorectal, hepatic, or pancreatic resection.

Secondary outcome

Secondary parameters are to explore:

1) individual responses to the program (physical fitness),

2) changes in immune system activity,

3) changes in nutritional status,

4) changes in quality of life,

5) changes in health status, and

6) short-term postoperative outcomes (e.g., and time to recovery of physical functioning, 30-day morbidity).

Study description

Background summary

Morbidity rates after resection of colorectal, hepatic, and pancreatic tumors are high. Frail patients often have less ability to cope with surgical stress and hospitalisation, which makes them more prone to complications. They require specific preoperative risk stratification in order to eventually tailor necessary preoperative interventions. Cardiorespiratory fitness, as indicated by the ventilatory anaerobic threshold (AT) assessed by a cardiopulmonary exercise test (CPET), can be used to identify high-risk patients (AT*11 mL/kg/min). Prehabilitation can improve the physical fitness of these high-risk patients before major abdominal surgery. However, there is limited evidence regarding the feasibility of home-based personalized prehabilitation program in high-risk patients opting for major abdominal surgery. We hypothesize that home-based personalized prehabilitation is safe with high program adherence/compliance and high patient appreciation.

Study objective

The primary objective of this one-group pre-test post-test pilot study is to assess the feasibility of a home-based personalized prehabilitation program of approximately four weeks (usual care) in high-risk patients scheduled for elective colorectal, hepatic, or pancreatic resection.

The secondary objective is to evaluate individual responses to prehabilitation regarding immune system activity, physical fitness, nutritional status, quality of life and health status (no cause-effect relationship to be established). Data on operative intervention, and postoperative recovery outcomes will also be collected for explorative purposes.

Study design

This study is a within subject non-experimental pre-post pilot study. The study will include high-risk patients (ventilatory AT*11 mL/kg/min) opting for elective colorectal, hepatic, or pancreatic resection at the Maastricht University Medical Center (Maastricht UMC+).

Intervention

Patients who provide informed consent will participate in a four-week (12 sessions in total) semi-supervised home-based personalized prehabilitation program. The program will be personalized to each patient (activities of relevance for the patient, progressed on intensity and repetitions, as well as on complexity and variability, and aiming to improve physical fitness and

physical functioning). The physical therapist will weekly monitor progress using non-sophisticated tests of functional exercise capacity, muscle strength, and functional mobility that can be easily executed in a home-based context in order to optimize the prehabilitation program. Before and after the program patients will perform a CPET (with blood sampling).

Study burden and risks

The risk for adverse events is considered negligible. Preoperative physical therapy (home-based prehabilitation program) for these high-risk patients is currently usual care at the Maastricht UMC+. In this explorative study, we collect extra data pre- and post prehabilitation to assess the feasibility and individual responses of this program. Physical training in patients with cancer is known to be safe and leads to improvements in physical fitness, as well as in quality of life. Before final inclusion in the study, a CPET will be performed to assess the baseline aerobic fitness, as well as to examine whether there are any contraindications for physical training (safety). The performance tests (e.g., CPET) are safe and non-invasive in these patients, as reported previously in studies of West et al. (2014), Heldens et al. (2017), and Levett et al. (2018).The venipuncture can give some bruising and hematoma at the venipuncture site. The prehabilitation program is usual care and will be personalized to each patient based on individual risk factors, preferences and goals. The training program itself will be executed at a moderate-to-high exercise intensity. With the weekly monitoring of progression, patients and their informal caregivers gain (extra) insight in their physical fitness and physical functioning (usual 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

- More that 18 years of age;
- Scheduled for elective colorectal, hepatic, or pancreatic resection at Maastricht UMC+;
- A low physical fitness according to the preoperative screening with the advice to participate in the hospital's prehabilitation program (usual care);
- Willing to participate in the hospital's prehabilitation program (usual care);
- Providing informed consent to participate;
- After informed consent, classified as being at risk for a complicated postoperative period (VAT *11 mL/kg/min at the pre-prehabilitation CPET).

Exclusion criteria

- Patients requiring acute (emergency) surgery;
- Patients undergoing surgery in another hospital than Maastricht UMC+;
- Patients with contraindications for physical exercise training;
- Unable to cooperate with the testing procedures (e.g., insufficient understanding of the Dutch language).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-05-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL65596.068.18