Preoperative home-based multimodal prehabilitation in patients scheduled for liver or pancreatic resection

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50320

Source
ToetsingOnline

Brief title
PRIOR study (PRehabilitation In Own Residence)

Condition

- Other condition
- Hepatobiliary neoplasms malignant and unspecified
- Therapeutic procedures and supportive care NEC

Synonym
liver and pancreatic tumours

Health condition

pancreas tumoren

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: via stichting wetenschappelijk onderzoek chirurgen Enschede en afdeling heelkunde UMCG.

Intervention

Keyword: anaerobic threshold, liver, pancreas, prehabilitation

Outcome measures

Primary outcome

The primary endpoint of this study is to assess the (preliminary) effectiveness of a 4-week home-based exercise training on an advanced cycle ergometer and the administration of nutritional supplements on preoperative cardiorespiratory fitness as measured by the anaerobic threshold in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection.

Secondary outcome

Secondary, we will investigate the feasibility of the prehabilitation program in this patient group by the registration of the number and severity of adverse events, adherence to the program, patient motivation before and after each training session, and patient appreciation questionnaire after four weeks.
Other secondary outcome measures include changes in quality of life before and after the prehabilitation program, changes in steep ramp test outcomes, the effect of the exercise program on the immune system, changes in other CPET values, individual changes in physical fitness during the prehabilitation program, and skeletal muscle metabolic function (energy metabolism). Data on operative intervention, perioperative outcomes and postoperative progress will

also be collected.

Study description

Background summary

The morbidity rates after resection of hepatic and pancreatic tumours are high. Older patients, especially the frail patients, are more prone to complications and require specific preoperative risk stratification. The anaerobic threshold (AT), assessed by cardiopulmonary exercise testing (CPET), can be used to identify high risk patients. Preoperative exercise prehabilitation can improve the physical condition of older patients before intra-abdominal surgery. There is limited evidence regarding the improvement of physical fitness after exercise prehabilitation in patients undergoing liver or pancreatic resection, and the feasibility of a prehabilitation program in these patients. Moreover, to enhance the anabolic effect of physical training, improve lean body mass and obtain or maintain an optimal nutritional status during the prehabilitation period, sufficient intake of nutrients is required. We hypothesize that multimodal prehabilitation (exercise program and nutritional supplements) will improve the preoperative anaerobic threshold, we assume to reach an average increase of 1.5 ml/kg/min, in patients with a low cardiorespiratory reserve (anaerobic threshold <11 ml/kg/min) undergoing elective liver or pancreatic resection.

Study objective

The primary objective is to assess the (preliminary) effectiveness of a 4-week home-based exercise training program on an advanced cycle ergometer and the administration of nutritional supplements on preoperative aerobic capacity as measured by the anaerobic threshold in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection. Secondary outcome measures include to assess the feasibility (adherence, adverse events, motivation, patient appreciation) of the 4-week home-based multimodal program, changes in other preoperative CPET measures, changes in preoperative quality of life score, effect of prehabilitation on the immune system by assessing biomarkers, individual changes in physical fitness and daily physical activity during the prehabilitation program, and skeletal muscle metabolic function (energy metabolism). Data on operative intervention, perioperative outcomes and postoperative progress will also be collected.

Study design

This study is a multicenter study with a pre- en posttest design. It will run from December 2017 until all patients are included, this will probably be in

June 2020. The study will take place in Medisch Spectrum Twente in Enschede, Universitair Medisch Centrum Groningen and Maxima Medisch Centrum. If informed consent is obtained from eligible candidates they will all receive the prehabilitation program before surgery. A small subgroup will be asked to perform a second, in-magnet, exercise test at various exercise intensities using a MR-compatible ergometer 1-2 days after the first and second CPET.

Intervention

Twenty-four patients will receive four weeks (12 sessions in total) of partly supervised home-based exercise training before surgery. An advanced cycle ergometer (Lode Corival, Lode BV, Groningen, the Netherlands) will be delivered at the patients* home. The training program, two sessions a week of interval training and one session a week of endurance training, twice combined with periphery muscle training, will be personalized to candidates. The physiotherapist will visit the patient three times a week in the first week, and once a week in week 2-4. Patients group will receive protein supplementation immediately following exercise and (± 30 minutes) before sleep, providing a standard dosage of 30 g of a high-quality (whey and casein) protein that contains at least 10 g of EAA, of which 2-3 g leucine. Moreover, patients will daily receive vitamin D and a multivitamin/mineral supplement. After the first CPET and prior to the second CPET blood samples will be collected, and interleukin (IL)-6, IL-8, IL-10, C-reactive protein (CRP), and tumor necrosis factor (TNF)-* will be measured. In a small subgroup (n=5), an additional, in-magnet, exercise test using an MR-compatible ergometer will be performed one or two days after each regular CPET to evaluate the effects of the prehabilitation program on skeletal muscle metabolic function (energy metabolism).

Study burden and risks

The risks associated with participation in this study are considered slightly increased, because the training program is partly unsupervised. But before the start of the training program a CPET will be performed under controlled condition under the guidance of trained employees to assess baseline cardiorespiratory fitness, as well as to examine whether or not there are contraindications for physical exercise training (safety). The prehabilitation program will be personalized to each patient based on individual steep ramp test results. The training program itself will be executed at a submaximal exercise intensity. We think the slightly increased risk is justified because of the expectation that the intervention will lead to better fitness and subsequently to better outcomes.

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

- Liver tumour (benign tumour, primary cancer, suspicion of a malignancy, or colorectal liver metastasis), or pancreatic tumour (pancreatic malignancy, premalignant pancreatic tumour or the suspicion of a pancreatic malignancy) requiring resection
- Undergoing elective liver (segmental resection or hemihepatectomy) or pancreatic surgery (pancreaticoduodenectomy, subtotal or total pancreatectomy)
- Having a life expectancy of more than 6 months
- Has given consent to participate in the study
- Metabolic equivalent score of *7 on the Veterans Specific Activity Questionnaire
- Anaerobic threshold <11 ml/kg/min after the first CPET
- Will be operated at Medisch Spectrum Twente at Enschede, Universitair Medisch

Centrum Groningen (UMCG) or Maxima Medisch Centrum (MMC)
- Living in Enschede, Oldenzaal, Losser, Lonneker or Glanerbrug

Exclusion criteria

- Not capable to cycle
- Not capable to perform a CPET
- Meeting the absolute and/or relative exclusion criteria from the CPET protocol used in Medisch Spectrum Twente, UMCG or MMC

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2018
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	21-04-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	06-02-2018

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-05-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2020
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: 27549
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL59702.044.16
OMON	NL-OMON27549