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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27549

Source
NTR

Brief title
Preoperative home-based multimodal prehabilitation

Health condition

In English: liver and pancreatic tumours.

In Dutch: lever en pancreas tumoren.

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Self-financing research: fund by department of surgery in Medisch Spectrum Twente and University medical centre of Groningen.

Intervention

Outcome measures

Primary outcome

The primary endpoint of this study is the (preliminary) effectiveness of the four-week home-based multimodal prehabilitation program in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection, to improve aerobic capacity.

Secondary outcome

Secondary objectives are:

- To evaluate the feasibility of a four-week home-based multimodal prehabilitation program in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection, as measured by adherence/compliance, adverse events, motivation, patient appreciation
- Does the prehabilitation program improve preoperative quality of life, as measured by the Short Form 36 (SF-36)?
- Does the prehabilitation program affect other CPET values reflecting aerobic capacity, such as the highest measured oxygen uptake (VO2peak), and oxygen uptake efficiency slope (OUES)?
- What is the (preliminary) effect of the prehabilitation program on the physical fitness of an individual patient, as assessed by results on the CPET, steep ramp test, and Lode ergometer data?
- What is the (preliminary) effect of prehabilitation on the immune system, by measuring IL-6, IL-8, IL-10, CRP, and TNF-α after the first and prior to the second CPET?
- What is the (preliminary) effect of prehabilitation on skeletal muscle metabolic function (energy metabolism)?
- Data on operative intervention, perioperative outcomes (i.e. morbidity, mortality, length of hospital stay) and postoperative progress will also be collected, to describe the perioperative course in patients after elective liver or pancreatic resection.

Study description

Background summary

Rationale: 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 in order to eventually tailor necessary prophylactic interventions. Aerobic capacity, as indicated by the anaerobic threshold assessed by a cardiopulmonary exercise testing (CPET), can be used to identify high-risk patients. Preoperative exercise prehabilitation can improve the physical fitness of high-risk patients before intra-abdominal surgery. There is however limited evidence regarding the improvement of aerobic capacity during and after exercise prehabilitation in patients undergoing liver or pancreatic resection. 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 aerobic capacity (anaerobic threshold <11 ml/kg/min) undergoing elective liver or pancreatic resection.
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 pretest – posttest design. It will run from December 2017 till December 2019 and it will take place in Medisch Spectrum Twente in Enschede, Universitair Medisch Centrum Groningen and Maxima Medical Center in Veldhoven. Potentially eligible candidates who provide informed consent will first undergo a CPET, receive a quality of life and health status questionnaire and venipuncture. Patients with an anaerobic threshold <11 ml/kg/min will participate in a personalized home-based multimodal prehabilitation program. After the prehabilitation program patients will undergo a second CPET, receive a quality of life and health status questionnaire, venipuncture, and an appreciation questionnaire. A small subgroup will be asked to perform a second, in-magnet, exercise test at various exercise intensities using a MR-compatible ergometer after the first and second CPET to evaluate the effects of the prehabilitation program on skeletal muscle metabolic function (energy metabolism).
Study population: Patients planned for elective resection of a liver or pancreatic tumor will be screened for potential eligibility. Patients with a metabolic equivalent score of ≤7 on the Veterans Specific Activity Questionnaire will be invited to participate in the study and will perform a CPET. Patients with an anaerobic threshold <11 ml/kg/min and no contraindications to physical exercise training as evaluated during the CPET can participate in the study.
Intervention: Twenty-four patients will participate in a four-week (12 sessions in total) of semi-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 at the cycle ergometer and one session a week of endurance training at the cycle ergometer, twice combined with peripheral muscle training, will be personalized to candidates. The physiotherapist will visit the patient at least weekly to monitor progress and to execute a steep ramp test to optimize the prehabilitation program. 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)-α 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).
Main study parameters/endpoints: The primary endpoint of this study is the (preliminary) effectiveness of the four-week home-based multimodal prehabilitation program in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection, to improve aerobic capacity. Secondary, the feasibility will be evaluated of the four-week home-based multimodal prehabilitation program in high-risk patients (anaerobic threshold <11 ml/kg/min) scheduled for elective liver or pancreatic resection, as measured by adherence/compliance, adverse events, motivation, patient appreciation. Other secondary endpoints are: 1) changes in other preoperative CPET measures, 2) changes in preoperative quality of life score, 3) effect of prehabilitation on the immune system, 4) individual changes in physical fitness and daily physical activity during the prehabilitation program, and 5) changes in parameters of skeletal muscle metabolic function (energy metabolism, small subgroup of patients).

Study objective

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 aerobic capacity (anaerobic threshold <11 ml/kg/min) undergoing elective liver or pancreatic resection.

Study design

At the first clinic attendance potentially eligible patients will be asked to participate in the study. A few days later they will be contacted and informed consent will be obtained. Patients who provide informed consent will undergo a CPET, receive a quality of life questionnaire and venipuncture at T0. Patients with an anaerobic threshold <11 ml/kg/min will participate in a personalized home-based multimodal prehabilitation program. After the prehabilitation program patients will undergo a second CPET, receive a second quality of life questionnaire, venipuncture, and an appreciation questionnaire at T1. A small pilot group of patients at the UMCG will undergo an in-magnet exercise test at various exercise intensities using a MR-compatible ergometer after the first and second CPET.

Intervention

Twenty-four patients will participate in a four-week (12 sessions in total) of semi-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 at the cycle ergometer and one session a week of endurance training at the cycle ergometer, twice combined with peripheral muscle training, will be personalized to candidates. The physiotherapist will visit the patient at least weekly to monitor progress and to execute a steep ramp test to optimize the prehabilitation program. 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)-α 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).

Contacts

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Eligibility criteria

Inclusion criteria

- Liver tumour (benign tumour, primary cancer, suspicion of a malignancy, or colorectal liver metastasis), 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
- VSAQ score ≤7 METs
- Anaerobic threshold <11 ml/kg/min at the first CPET
- Will be operated at MST, UMCG or MMC
- Living in Enschede, Oldenzaal, Losser, Lonneker or Glanerbrug (in case of inclusion in MST)

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 MST or UMCG. These criteria are based on the criteria from the American Thoracic Society and American College of Chest Physicians Statement on CPET.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2017
Enrollment:	24
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-03-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50320
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6151
NTR-old	NTR6282
CCMO	NL59702.044.16
OMON	NL-OMON50320

Study results

Summary results
None.