Cardiac and intramuscular adaptations following short-term exercise prehabilitation in unfit patients scheduled to undergo hepatic or pancreatic surgery

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The main objective is to assess the central (cardiac function) and peripheral (skeletal muscle function) physiological adaptations in response to exercise prehabilitation.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON53378

Source
ToetsingOnline

Brief title
CIRCULATE

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
hepatopancreatobiliary malignancies, liver, pancreas and bile duct tumours

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nationaal Fonds tegen Kanker

Intervention

Keyword: Hepatic, Pancreatic, Prehabilitation, Surgery

Outcome measures

Primary outcome

The difference in left and right ventricular function will be measured by exCMR in rest, during progressive exercise, and recovery to assess the effect of the preoperative physical exercise training program on cardiac function. The difference in quadriceps phosphocreatine concentration (PCr), quadriceps inorganic phosphorus concentration (Pi), and quadriceps pH at rest, during progressive exercise, and recovery rate will be measured by 31P-MRS to assess the effect of the prehabilitation program on skeletal muscle function.

Secondary outcome

Not applicable.

Study description

Background summary

Surgery remains an important treatment modality in the treatment of hepatopancreatobiliary (HPB) malignancies, but the physiological stress caused by surgery is at the same time a challenge for the homeostasis of patients. A patient*s preoperative aerobic capacity has been found to have a consistent relation with postoperative outcomes in major abdominal surgery, with low aerobic capacity being associated with a higher risk of postoperative morbidity and mortality. Preoperative exercise prehabilitation programs can effectively increase the ability of patients to cope with surgical-induced allostatic load, by improving aerobic capacity, and functioning of the respiratory,

cardiovascular, and/or musculoskeletal systems. However, besides the effect of exercise prehabilitation on physical fitness in terms of improvement of aerobic capacity as measured by the cardiopulmonary exercise test (CPET), the exact role of adaptations in cardiac and/or skeletal muscle function contributing to the improvement in aerobic capacity is still unknown. Insight in the physiological adaptations that lead to improvement in aerobic capacity after prehabilitation in patients with low aerobic capacity will enable caregivers to individually optimize the exercise program (e.g. by changing exercise frequency, intensity, duration and type) and better explain the rationale and effectiveness behind the short-term physical exercise training program to patients.

Study objective

The main objective is to assess the central (cardiac function) and peripheral (skeletal muscle function) physiological adaptations in response to exercise prehabilitation.

Study design

This study is a single center prospective clinical trial with a one-group pretest-posttest design. It will take place at the University Medical Center Groningen (UMCG), the Netherlands. As part of standard care all patients scheduled to undergo hepatic or pancreatic surgery for (suspected) HPB malignancies at the UMCG are screened for low aerobic capacity, and subjected to exercise prehabilitation in case of low aerobic capacity. In this study, unfit patients are asked to undergo additional in-magnet exercise testing to investigate the central and peripheral physiological adaptations in response to exercise prehabilitation. In-magnet exercise test consisting of in vivo exercise Cardiac Magnetic Resonance (exCMR) imaging and 31P-Magnetic Resonance Spectroscopy (31P-MRS) during exercise testing in a MR-compatible ergometer, before and after the 4-week prehabilitation program.

Study burden and risks

The intervention consists of two extra hospital visits. During these visits the in-magnet exercise tests (exCMR and 31P-MRS) will be performed. Patients will perform an exCMR and 31P-MRS before and again after the exercise prehabilitation program. The in-magnet exercise test can lead to physical discomfort, due to an uncomfortable feeling while cycling on an ergometer whilst laying supine in the MRI. Before the in-magnet exercise test, a CPET in a controlled environment (continuous 12-lead electrocardiography registration and under supervision of a sports physician) is performed and therefore the in-magnet exercise test can be safely performed when the CPET does not show contra-indications for exercise. The imaging consisting of exCMR and 31P-MRS has previously been shown to be safe and is already widely used in different

studies. Patients are not exposed to any radiation and/or contrast agents.

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

- VO2 at the ventilatory anaerobic threshold (VAT) <=13 ml/kg/min and/or VO2peak <=18 ml/kg/min, as determined during the baseline CPET;
- More than 18 years of age;
- Scheduled for elective liver- or pancreatic resection at the UMCG;
- Willing to participate in the home-based bimodal prehabilitation program;
- Has given consent to participate in the study

Exclusion criteria

- Patients requiring acute (emergency) surgery;
- Patients not capable of cycling on a cycle ergometer;
- Patients with contraindications to physical exercise training;
- Patients receiving neoadjuvant chemotherapy
- Contraindications for exCMR (e.g., claustrophobia, implanted cardiac devices)
- Atrial fibrillation or other significant arrhythmia during the exCMR and 31P-MRS procedures;
- Body weight >140 kg;
- Body length > 190cm
- History of myocardial infarction, percutaneous coronary intervention or coronary artery bypass graft <3 months or untreated severe obstructive coronary artery stenosis;
- More than moderate left-sided valve disease;
- Complex congenital heart disease.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2024
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2023

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL83611.042.23