Preoperative pREhabilitation in patients planned for LIVER Transplantation

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON56969

Source
ToetsingOnline

Brief title
PRELIVERT

Condition

- Hepatic and hepatobiliary disorders

Synonym
Liver cirrhosis, liverdisease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Daniel den Hoed fonds

Intervention

Keyword: Lifestyle, Liver, Prehabilitation, Transplantation

Outcome measures

Primary outcome

The main study parameter/endpoint is the feasibility of the prehabilitation program (program satisfaction, compliance, and percentage of patients willing to participate in the prehabilitation program).

Secondary outcome

-Physical outcomes (functional capacity, aerobic capacity, daily physical acitvity levels, hand grip strength, and quadriceps strength)

-Nutritional outcomes (nutritional status, body composition)

-Psychosocial outcomes (health status, anxiety and depression, self-efficacy)

-Substance abuse (smoking, alcohol consumption)

-Post operative outcomes (length of hospital stay, complications in first 30 days, readmission rate in first 30 days)

Study description

Background summary

Patients who qualify for liver transplantation (LT) are mostly frail due to their underlying liver disease. Frailty is comprised by a decreased functional capacity, impaired aerobic capacity, and sarcopenia. It is well known that frailty leads to both increased pre- and post-transplantation morbidity as well as mortality. For various surgical populations prehabilitation was demonstrated to be feasible, effective, and to improve surgical outcomes. Few studies on this subject have been conducted in the patient population awaiting liver transplantation.

Study objective

The primary objective is to determine the feasibility of a semi-supervised homebased prehabilitation program for patients to be waitlisted for LT. The secondary objectives are to assess the effectiveness of this program and possible improvements of surgical outcomes (e.g. less complications, faster recovery, and shorter length of hospital stay).

Study design

This is a single-centre, single arm, prospective cohort study.

Intervention

Patients will participate in an eight-week semi-supervised home based prehabilitation program. This program consists of physical exercise, nutritional support provided by a dietician, smoking cessation, and psychological counselling. The program will be personalized and consists of two training sessions per week. Through a digital *Oefenportaal* platform the physical therapist will supervise the exercises and monitor patients* adherence to the program.

Study burden and risks

Patients will participate in an eight-week prehabilitation program prior to anticipated LT. The prehabilitation sessions take approximately 3-5 hours per week. In order to lower the burden for patients the majority of the program takes place at home using digital tools. During the first week patients are seen at the Erasmus MC for an intake (about 60 minutes). All study appointments will be combined with regular appointments for screening if possible. Furthermore, patients are expected on-site at the start and after completion of the prehabilitation program to undergo measurements (90 minutes). Also, they have to complete questionnaires at home three times total (two times 20 minutes, one time 10 minutes).
Since the prehabilitation program is based on existing care, we expect minimal risks for the patients. Participants are anticipated to benefit from the prehabilitation program considering a better physical fitness and a behavioural change towards a healthier lifestyle.

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

Anticipated waitlisting for liver transplantation

Exclusion criteria

1. Patients with severe physical or psychological comorbidities that limit participation in the prehabilitation program
2. Acute or acute-on-chronic liver failure

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-10-2024
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	27-08-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85306.078.23