Prehabilitation to enhance postoperative recovery after live kidney donation

Published: 11-04-2018
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The aim of this study is to evaluate logistic challenges in including and treating donors in a prehabilitation programme.

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

Summary

ID

NL-OMON46681

Source
ToetsingOnline

Brief title
PACE study

Condition

- Other condition

Synonym
prehabilitation - recovery after surgery

Health condition

zijn gezonde donoren en hebben geen aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: living donors, quality of life, recovery of Function, sports

Outcome measures

Primary outcome

Logistic challenges in including and treating donors in a prehabilitation programme

Secondary outcome

Measuring fatigue symptoms after live kidney donation in terms of quality of life questionnaires (SF-36 ACUTE VERSION, MVI-20). Outcome in terms of aerobic capacity (VO2 Max), anaerobic capacity (Wpeak), monitoring physical activity, intramuscular glycogen turnover, postoperative complications (wound infection, re-admissions to hospital, lung infection, bladder infection) and return to work.

Study description

Background summary

Kidney donors are healthy individuals who donate their kidney to patients with end-stage renal disease. Fatigue after kidney donation is a common complaint that affects the quality of life after kidney donation and delayed return to daily practice. A recent systematic review shows that the quality of life only returns to baseline or was slightly reduced at 3 to 12 months after donation, particularly for fatigue. A surgical procedure is a stress factor for patients and the impact on their physical condition can reduce quality of life. The physical condition of a patient is a predictive factor for postoperative outcomes. Improving the physical activity of the donor prior to surgery by means of a prehabilitation programme may lead to improve physical condition during surgery and faster recovery postoperatively.

Study objective

The aim of this study is to evaluate logistic challenges in including and treating donors in a prehabilitation programme.

Study design

In this pilot study, we will include 10 healthy people (>18 years) who are listed to undergo a live donor nephrectomy at the Erasmus Medical Center.

Intervention
supervised SIT training twice a week for a minimum of 6 weeks prior to donation

Intervention

Sprint Interval Training (SIT)
The SIT intervention that the subjects will undergo is a sprint test on a specific bike (High Octane Ride Bike by Matrix). This sprint test consists of 3 minutes of unloaded pedaling (30 rpm) followed by a set time of 20 seconds pedaling at a maximum speed against a constant resistance equivalent to 4-7.5% of bodyweight. This will be done twice with 3 minutes of unloaded pedaling (30 rpm) after each sprint. The total SIT workout will be 9 minutes and 40 seconds; with netto intervention of 40sec all out sprint.

Study burden and risks

Several standardized questionnaires are asked to be filled in before, during and after the SIT in order to measure fatigue and quality of life. The questionnaires take 2-10 minutes to complete. No serious side effects are expected the prehabilitation program.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Eligible live kidney donor
- Age above 18 years
- Meet American College of Sports Medicine (ACSM) guidelines for basic physical activity levels
- Minimum of 6 weeks prior to donation
- Written informed consent

Exclusion criteria

- Unable to read, write and understand Dutch language
- Preoperatively physical disabilities (e.g. sport injuries)

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):	28-02-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	11-04-2018
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	NL62977.078.17