Physical Exercise Prehabilitation Program in mEtabolic suRgery

Published: 23-02-2021
Last updated: 21-12-2024

The aim of this study is to investigate whether prehabilitation could enhance preoperative physical condition and weight loss before bariatric surgery and induce a lifestyle behavior change.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON54307

Source
ToetsingOnline

Brief title
PEPPER trial

Condition

- Metabolism disorders NEC
- Gastrointestinal therapeutic procedures

Synonym
morbid obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Flevoziekenhuis
Source(s) of monetary or material Support: Flevoziekenhuis

Intervention

Keyword: bariatric surgery, Physical condition, postoperative outcome, prehabilitation

Outcome measures

Primary outcome

The initial primary outcome will be preoperative physical condition by using the 6-minute walking test (6MWT). The 6MWT is measured at the beginning of the prehabilitation program (baseline) and after the prehabilitation program (group 1). For the control group the 6MWT is measured at baseline and after 2 months.

Secondary outcome

Secondary outcomes will include the Comprehensive Complication Index (CCI) for post-operative outcome (Clavien-Dindo class III-V complications), length of hospital stay (LOS), preoperative weight loss, Excess Weight Loss (excess weight = actual weight * ideal weight) and percentage excess BMI loss at 1 year postoperative, satisfaction of the prehabilitation program by an questionnaire and we will measure physical activity at baseline and 1 year postoperative with the NNGB questionaire. Furthermore we will measure health related Quality of Life with the RAND-36 questionnaire at baseline and 1 year postoperative.

Study description

Background summary

Obesity is a major public health burden and there are many national health programs to encounter this problem. Bariatric surgery is the most effective intervention in obese adults who do not respond to conservative treatment. People with obesity have high surgical risk and long-term outcomes are related

to preoperative physical condition and preoperative weight. Evidence shows that the preoperative period is the optimal moment for intervention. This study will determine the impact of prehabilitation on bariatric patients* preoperative physical condition and postoperative outcomes.

Study objective

The aim of this study is to investigate whether prehabilitation could enhance preoperative physical condition and weight loss before bariatric surgery and induce a lifestyle behavior change.

Study design

This, prospective, randomized controlled trial will include 58 patients undergoing bariatric surgery. Patients will be divided in two groups: the intervention group (group 1) will receive 8 weeks of prehabilitation and standard preoperative counseling with a dietician and the control group (group 2) will only receive preoperative counseling with a dietician.

Intervention

The intervention that is given to the intervention group is: 8 weeks of prehabilitation, exercise two times a week in a group setting supervised by a physiotherapist.

Study burden and risks

Both groups of patients will receive regular care. This includes a mandatory screening of the dietician, psychologist, nurse and surgeon followed by the bariatric multidisciplinary team (BMDT) meeting to decide on the patient's individual treatment strategy. If necessary, patients will receive extended consultations from the dietician or psychologist. Within this study: The intervention group receives a prehabilitation program of eight weeks, exercise two times a week in a group setting. Risks associated with this intervention are sports injuries. A possible benefit of particpants in the prehabilitation group could be: more fit before surgery, may lead to decreased postoperative complications. Overall, the complication rate after bariatric surgery is low. The overall complication rate after bariatric surgery is approximately <1%.

Contacts

Public
Flevoziekenhuis

Hospitaalweg 1
Almere 1315RA
NL
Scientific
Flevoziekenhuis

Hospitaalweg 1
Almere 1315RA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Adult patients (>18 years) were eligible for inclusion if their body-mass index (BMI) was 40 kg/m2 or higher, or 35 kg/m2 or higher with the presence of at least one comorbidity (type 2 diabetes, high blood pressure, heart and / or vascular diseases, obstructive sleep apnea (OSA), dyslipidemia, or arthritis. For inclusion we will follow our National Guidelines on metabolic surgery.

Exclusion criteria

previous bariatric surgery
patients with/who:
1. mobility problems (patients who are not able to exercise)
2. cognitive disabilities
3. illiteracy (patients who are not able to read)
4. do not understand the Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2022
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL74088.018.20