Effect of protein supplementation on fat free mass preservation after bariatric surgery, a randomized double-blind placebo-controlled trial.

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The main aim of this study is to assess whether protein supplementation could prevent excessive fat free mass loss during the first year after bariatric surgery.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON51327

Source
ToetsingOnline

Brief title
PROMISE-study

Condition

- Appetite and general nutritional disorders
- Muscle disorders
- Gastrointestinal therapeutic procedures

Synonym
gastric bypass, stomach reduction

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Fit For Me,vakgroep chirurgie

Intervention

Keyword: bariatric surgery, fat free mass, muscle mass, protein supplementation

Outcome measures

Primary outcome

The main study parameter is the percentage fat free mass loss six months after surgery, calculated as fat free mass loss (kg) divided by total fat free mass (kg) before surgery. Fat free mass will be assessed by multi-frequency bioelectrical impedance analysis (MF-BIA).

Secondary outcome

Secondary parameters are total weight loss, BMI before and after surgery, fat mass, hand grip strength, physical activity and total protein intake.

Study description

Background summary

Protein malnutrition is a severe complication of bariatric surgery and leads to increased morbidity. Previous studies have shown that protein intake and physical activity are the most important factors in the preservation of fat free mass during weight loss. Low protein intake is very common in patients undergoing bariatric surgery despite dietary counselling. Protein powder supplements might help patients to achieve the protein intake recommendations after bariatric surgery and could therefore contribute to preserve fat free mass.

Study objective

The main aim of this study is to assess whether protein supplementation could prevent excessive fat free mass loss during the first year after bariatric

surgery.

Study design

a randomized double-blind placebo-controlled trial

Intervention

Inclusion will take place at the outpatient clinic of the bariatric expertise center of the Maasstad Hospital. Patients will be randomly assigned to either the intervention or control group before surgery. The intervention group will receive a clear protein powder shake of 200 ml containing 20 grams of whey protein which should be taken daily during the first six months after LRYGB. The control group will receive an isocaloric, clear, placebo shake containing maltodextrine.

Study burden and risks

No additional outpatient visits will be required for study participants. A three day food diary and physical activity questionnaire must be filled out by all study participants at five regular follow-up moments. Body composition and handgrip strength will be assessed during these visits. All study participants will be asked to drink a daily shake, either protein or placebo, integrated in their postoperative diet. Study participants will receive information about the changes in body composition after surgery which is considered to be a significant benefit for patients participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients who undergo bariatric surgery.

Exclusion criteria

- Revisional bariatric surgery
- A protein-restricted diet for medical reasons
- Diagnosis of a (neuro-) muscular disease
- Inability to undergo MF-BIA (i.e. pregnancy, pacemaker)
- Allergy to any of the ingredients of either the protein or the placebo shake

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-09-2022
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	09-05-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80414.100.22