

Comparison of preoperative diets before bariatric surgery: a randomized controlled trial

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Comparison of preoperative diets before bariatric surgery with a randomized non-inferiority trial in order to compare the standard VLCD with a standard diet.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36832

Source

ToetsingOnline

Brief title

RCT of preoperative diets before bariatric surgery

Condition

- Gastrointestinal therapeutic procedures

Synonym

Morbid obesity

Research involving

Human

Sponsors and support

Primary sponsor: Lievensberg ziekenhuis

Source(s) of monetary or material Support: Geen financiering

Intervention

Keyword: Bariatric, diets, preoperative, RCT

Outcome measures

Primary outcome

Weight loss (in kg) before operation

Secondary outcome

- operation time
- blood loss
- difficulty of procedure
- short term complications
- acceptance of diets according to patients

Study description

Background summary

Morbid obesity, defined as a body mass index (BMI) of $> 40 \text{ kg/m}^2$ or $> 35 \text{ kg/m}^2$ with obesity-related comorbidities, is a rapidly growing problem in the western society. In the United States, about 6 million people currently have a BMI of $> 40 \text{ kg/m}^2$ and another 10 million people have a BMI of $> 35 \text{ kg/m}^2$ with comorbidities. Worldwide, the incidence of morbid obesity has doubled and about 300 million people are now obese [1, 2]. In the Netherlands the prevalence is less disturbing but the incidence of morbid obesity is rising progressively to 1.5% of the total population [3]. At this moment surgical therapy is the only treatment option for these patients that results in sufficient long-term weight loss. Non-surgical approaches, like low energy diets and behavior modification, are not successful in the long-term with respect to maintaining weight loss and decreasing obesity-related comorbidities[4, 5].

In order to increase weight loss and minimize complications a preoperative diet before bariatric has been advocated. However, the usual VLCD's are poorly tolerated by patients. In this study we aim to compare two preoperative diets in order to find the most suitable for this patient population.

Study objective

2 - Comparison of preoperative diets before bariatric surgery: a randomized controll ... 7-05-2025

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Study design

Randomized clinical trial of two preoperative diets before bariatric surgery (gastric bypass) comparing standard diet and Prodimed

Intervention

Preoperative diet

Study burden and risks

No risks.

Burden: 1 questionnaire, 1 diet book filled out during 10 days and 1 extra OPD visit.

Total: 120 minutes

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- BMI >40 kg/m² or >35 kg/m² with serious comorbidities
- after multidisciplinary consensus reached for gastric bypass surgery

Exclusion criteria

- psychologically unsuitable according to psychologist (i.e. serious psychiatric disorders)
- serious cardiopulmonary pathology (ASA 3 or higher)
- former gastric / bariatric procedures
- age < 18 or > 60 years

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-10-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date: 28-09-2012

Application type: First submission

Review commission: TWOR: Toetsingscommissie Wetenschappelijk Onderzoek
Rotterdam e.o. (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	NL41186.101.12