Effect of preoperative weight loss with a 14-day low-calorie diet on surgical procedure and outcomes in patients undergoing RYGB surgery.

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The primary objective is to evaluate the effect of preoperative weight loss (by means of a 14-day low-calorie diet) on the operative time of the RYGB procedure. The first secondary objective is to evaluate the effect of preoperative weight loss on…

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

Summary

ID

NL-OMON49715

Source
ToetsingOnline

Brief title
PREBA study

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery, weight loss surgery

Health condition

Morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: eigen middelen Vitalys

Intervention

Keyword: Gastric Bypass, Obesity, Preoperative diet, Weight loss

Outcome measures

Primary outcome

The primary study outcome is the difference in operative time of the RYGB procedure between the intervention and control group, retrieved from electronic medical records after surgery.

Secondary outcome

1. The first secondary outcome is the difference in (perceived) ease of the RYGB procedure between the intervention and control group, assessed by a surgery score sheet. This surgery score sheet was constructed in cooperation with surgeons and is based on the subsequent steps of the RYGB procedure.

2. The second secondary outcome is the difference in postoperative weight loss between the intervention and control group, assessed by body weight measurements during regular follow-up visits.

The tertiary outcome of this study is the feasibility, compliance and safety of the diet. We will asses if the diet can be implemented in the standard nutritional care procedure for bariatric patients at Vitalys. Opinion of both

patients and dietitians will be taken into account. Besides, short term

complication rates and degree of wound healing will be used as an indication

for safety.

Study description

Background summary

Bariatric surgery is the most effective method of treating morbid obesity, of which RYGB is one of the most commonly performed bariatric procedures. Bariatric guidelines recommend a preoperative weight loss of 5%, to reduce the risk of operative complications. Many bariatric centres already advice patients to lose weight before they undergo surgery by recommending a preoperative diet. Nevertheless, Vitalys, one of the largest bariatric surgery clinics, does not require their patients to follow a preoperative weight loss diet, as the results in the literature on the improvement of surgical procedure and outcomes are still contradicting. We hypothesise that preoperative weight loss (by following a 14-day low-calorie diet) will improve the operative time, ease of the RYGB procedure and postoperative outcome on long-term weight loss, in comparison to the standard nutritional care of Vitalys.

Study objective

The primary objective is to evaluate the effect of preoperative weight loss (by means of a 14-day low-calorie diet) on the operative time of the RYGB procedure.
The first secondary objective is to evaluate the effect of preoperative weight loss on the (perceived) ease of the RYGB procedure.
The second secondary objective is to evaluate the effect of preoperative weight loss on postoperative weight loss (up to 5 years).
The tertiary objective is to evaluate if the diet can be implemented into the standard nutritional care procedure for bariatric patients undergoing surgery at Vitalys. This will be based on patients' experiences and compliance, experiencies of the dietitians and short term complication rate (within 30 days) and degree of wound healing 4 weeks post-surgery.

Study design

This experimental study will use a two-arm randomised single-blind controlled trial design to evaluate the effect of preoperative weight loss (by following a 14-day low calorie diet) on the operative time and ease of RYGB procedure and postoperative outcomes on long-term weight loss, and compare this to the

standard nutritional care procedure. A total of 80 patients undergoing RYGB surgery will be recruited at Vitalys, Rijnstate Hospital Arnhem and patients will be randomly assigned to the intervention group (n=40) or control group (n=40).

Intervention

The intervention group (n=40) will follow a 14-day low-calorie diet, providing about 900 kcal (women) and 1000 kcal (men) a day by using meal replacements. The control group (n=40) will follow the standard nutritional care procedure (no diet).

Study burden and risks

The risk of participating in this study is small and the burden is kept to a minimum, as following an energy-restricted preoperative diet is assumed to be harmless and is clinical practice in many other bariatric centres. The meal replacements that participants will receive can be prepared at home. Participants will be asked to complete a food and physical activity diary and will be contacted twice to conduct a short diet feasibility questionnaire by phone. The anthropometric measurements will mostly take place during the regular visits at the hospital or dietitian. The entire study may imply max one extra visit.
With this study, we expect to show that preoperative weight loss (by means of a 14-day low-calorie diet) will effectively improve the operative time, the ease of the RYGB procedure and postoperative outcomes on long-term weight loss.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Next to the general inclusion criteria for undergoing bariatric surgery, participants must meet all the following criteria:
• 18-65 years
• Undergoing primary RYGB surgery at Vitalys, Rijnstate Hospital (meeting all criteria for undergoing RYGB + approval of surgeon)
• Able to prepare meal replacements at home

Exclusion criteria

Participants are excluded from the study if they meet any of the following criteria:
• Undergoing another bariatric procedure than primary RYGB.
• Diabetes Mellitus
• Having contraindication for the usage of the meal replacements (e.g. allergy or intolerance to any substance in the used meal replacements, veganism or suffering from kidney failure, liver failure, cardiac insufficiency, cancer, hypokalaemia or phenylketonuria and porphyria

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2020
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-05-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70092.081.19