The impact of a preoperative very low calorie ketogenic diet (VLCKD) on body composition in patients undergoing bariatric surgery: an open trial

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The main objective of the proposed study is to investigate the effect of a VLCKD on body composition in patients undergoing bariatric surgery, and to compare this with a standard VLCD.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51676

Source
ToetsingOnline

Brief title
Ketogenic diet prior to bariatric surgery

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Morbid obesity

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Maxima Medisch Centrum

Intervention

Keyword: Bariatric surgery, Body composition, Very low calorie ketogenic diet, VLCKD

Outcome measures

Primary outcome

The reduction in FFM expressed in percentages in proportion to total body weight loss, from baseline to 2 weeks after start of the diet, as confirmed by multifrequency (MF) BIA and by Dual-energy X-ray Absorptiometry (DXA).

Secondary outcome

• Weight, measured by MF-BIA and DXA

• Body composition (FM, LBM and RMR)

• Total body weight loss

• Muscle strength, measured by handgrip peak strength

• Compliance, side effects and food intake, measured by self-reported questionnaires and interviews

• Surgical outcomes including surgical time, hospital stay, complications and re-admissions occurring within 30 days postoperative

• Biochemical tests including B-hydroxybutyrate, albumin, electrolytes (sodium, potassium), liver function (AST = Aspartate Aminotransferase, ALT = Alanine Transaminase, GGT = gamma glutamyl transpeptidase), kidney function (creatinine, urea, eGFR), iron and hemoglobin, metabolic profile (total

cholesterol, LDL = low-density lipoprotein, HDL= HDL*high-density lipoprotein,

triglycerides), calcium, glucose.

• Physical activity, measured by International Physical Activity Questionnaire

(IPAQ)

• Patient satisfaction (5-point Likert scale: not at all satisfied, slightly

satisfied, neutral, very satisfied and extremely satisfied)

Study description

Background summary

Bariatric surgery is considered the most effective treatment for severe obesity as it promotes significant long-term weight loss and improves or even resolves obesity-related comorbidities. Preoperative weight loss is frequently advised to overcome technical challenges during surgery. It may furthermore improve short-term outcomes like surgical time, blood loss, hospital stay and postoperative complications, as well as long-term outcomes like weight loss. Preoperative weight loss can be realised by dietary regimens, like low-calorie diets (LCD) (800-1500 kcal/day) and very low-calorie diets (VLCD) (<800 kcal/day). Downfalls of such diets are a loss of metabolically active fat free mass (FFM), in continuing presence of an excessive fat mass, and some patients may not tolerate a (V)LCD regime due to side-effects leading to poor compliance and subsequently poor weight loss outcomes. Very low-calorie ketogenic diets (VLCKD) have been proposed as a new diet for patients undergoing bariatric surgery. VLCKD is characterized by a very low carbohydrate content (<50 g/daily), a low fat content (15-30 g fat/daily) and a high amount of proteins (1-1.5 g protein/kg ideal body weight). The beneficial effect of VLCKDs compared to (V)LCDs is the aimed preservation of FFM and therefore resting metabolic rate, while still reducing fat mass. In addition, the compliance of patients might be improved by VLCKDs, possibly thanks to the anorexigenic effect and hunger reduction of ketone bodies. In our current care pathway patients will start the VLCD two weeks prior to their scheduled RYGB. Only a few small studies addressed the role of VLCKDs prior to bariatric surgery. Therefore, we propose a randomised controlled trial to establish the efficacy of a VLCKD compared to the standard VLCD.

Study objective

The main objective of the proposed study is to investigate the effect of a

VLCKD on body composition in patients undergoing bariatric surgery, and to compare this with a standard VLCD.

Study design

An open trial with an hypothesised sample size of 46 patients.

Intervention

Control group:
The control group will receive the regular VLCD (standard care), two weeks prior to their scheduled RYGB

Intervention group:
The intervention group will receive the VLCKD, two weeks prior to their scheduled RYGB

Study burden and risks

Burden:
- A burden that patients may experience from this research is that their appointments in the hospital can take longer. Carrying out body composition studies takes time, and filling in the questionnaires also takes time. They will be in the hospital approximately 45 minutes longer because of this. Patients will receive up to 3 extra check-ups for which they will have to fill in questionnaires several times. Patients do not have to visit the hospital extra for this, as these coincide with the standard hospital visits already planned or these questionnaires can be completed from home.

- Additional blood test are needed. In our current care path, patients only need to undergo one blood test. In this study there will be an additional blood test necessary.

Risks:
- The diet to be studied may have side effects. Side effects that patients may experience from the ZLCKD diet include bad breath, headache, dry mouth, dizziness, low blood sugars (hypoglycemia) and decreased energy and hyperuricemia. These side effects can also occur with normal diets. Another side effect that can occur, which is very rare, but should be mentioned, is that a patient has a slightly increased risk of kidney stones and possible gout attacks.

Due to the ZLCKD diet, the patient ensures that the blood sugar remains at a more stable level and will not experience highs and lows, because patients eat almost no carbohydrates, but the metabolism depends on fats and proteins. This

could mean that patients can endure a slightly higher chance of a hypoglycemia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Patients with the age of 18-65 years are included if they are scheduled for a primary laparoscopic Roux-en-Y gastric bypass (RYGB) because of severe obesity. The latter is classified as a body mass index (BMI) of >=35 kg/m2 with obesity-related comorbidities, or a BMI of >=40 kg/m2 with or without comorbidities

Exclusion criteria

• Weighing over 150kg because this amount is a limitation by the DXA device
• Diabetes mellitus type 1
• Allergic to milk proteins
• A recent history of a heart attack (< 12 months), heart failure or cardiac arrhythmias
• Kidney and/or liver failure (creatinine levels >1.3 mg/dl or liver enzyme levels (AST, ALT, GGT) less than three times over the upper normal threshold
• Current infectious, sepsis or malignant disease
• Rare condition like galactosemia, phenylketonuria or porphyria
• Persistent diarrhoea
• Hypokalaemia, chronic therapies with diuretics as furosemide and hydrochlorothiazide
• Pregnancy or plans to get pregnant in the coming months
• Patients who did not meet criteria to be eligible for bariatric surgery (BMI <35, psychological or unstable psychiatric disorders, inadequate dietary regimen or inadequate exercise pattern which can*t be resolved in the upcoming 6 months)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2022
Enrollment:	46
Type:	Anticipated

Ethics review

Approved WMO Date:	08-11-2022
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL81550.015.22