

Effects of two preoperative weight loss diets on hepatic volume and surgical complications in morbid obese bariatric surgery candidates

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| Submission date 19/02/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 23/02/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 30/08/2018 | Condition category Surgery | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The aim of this study is to assess which type of dietary strategy is the most effective for patients with morbid obesity who are about to undergo weight loss (bariatric) surgery. It is thought that a low calorie diet will be more effective than a very low calorie diet (e.g. it will reduce surgical complications and length of hospital stay).

Who can participate?

Patients with morbid obesity undergoing bariatric surgery

What does the study involve?

Participants are randomly allocated to follow a very low calorie diet or a low calorie diet for 21 days before surgery. Body measurements, blood parameters, liver volume by CT scan, and compliance with the intervention are measured before and after the intervention.

What are the possible benefits and risks of participating?

In the short term, it is not expected that the results obtained may directly benefit the participant, although they could be of interest for future patients undergoing bariatric surgery. The study does not pose any additional risk apart from providing blood samples and undergoing CT scans.

Where is the study run from?

Hospital Universitari Sant Joan de Reus (Spain)

When is the study starting and how long is it expected to run for?

September 2014 to July 2017

Who is funding the study?

Nestle S.A.

Who is the main contact?

Dr Jordi Salas Salvado

Contact information

Type(s)

Scientific

Contact name

Dr Jordi Salas Salvado

Contact details

Human Nutrition Unit, Faculty of Medicine and Health Sciences

Universitat Rovira i Virgili

C/Sant Llorenç 21

Reus

Spain

43201

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14-09-18/9proj4

Study information

Scientific Title

Effects of two preoperative weight loss diets on hepatic volume and surgical complications in morbid obese bariatric surgery candidates: a randomized clinical trial

Study objectives

Pre-operative weight loss in patients with morbid obesity candidates for bariatric surgery through the use of a Low Calorie Diet (LCD) will be more effective than a Very Low Calorie Diet (VLCD) on the preservation of protein and immune status, reduction of surgical complications, hospital stay and will be equally effective in terms of reduction in liver volume.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical committee of the University Hospital Sant Joan de Reus, 29/01/2015, CEIC reference project: 14-09-18 / 9proj4, reference CEIC esmena: 15-01-29 / 1esmproj1

Study design

Single-center randomized parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Influence of two types of pre-surgery diets on the decrease of hepatomegaly in morbidly obese candidates for bariatric surgery

Interventions

Subjects will be randomized with a 1:1 ratio using an excel randomization table to follow a very low calorie diet (VLCD) or a low-calorie diet (LCD) for a period of 21 days. Both dietary interventions had the same percentage of macronutrients (46.8% carbohydrates, 36.4% protein, 9.3% fat, and 7.4% fiber). The total amount of energy administered with the VLCD (4 sachets of Optifast®; Nestlé Health Science; 2011) will be 800 kcal/day, broth and non-calorie beverages allowed. The LCD diet consisted of a defined fixed diet containing 1200 kcal/day also using two sachets of Optifast®.

Intervention Type

Mixed

Primary outcome measure

Hepatic volume through computed tomography at baseline and 21 days after dietary intervention

Secondary outcome measures

1. Body weight and anthropometry parameters at baseline and at 21 days of intervention
2. Leukocyte count and serum albumin, prealbumin and total proteins at baseline and at 21 days of intervention
3. Renal and hepatic function parameters at baseline and at 21 days of intervention
4. Surgery complications (between surgery until 6 months after surgery) and hospital stay length (during the hospital stay)
5. Dietary compliance and acceptability, assessed weekly during the first 3 weeks of the intervention

Overall study start date

01/09/2014

Completion date

31/07/2017

Eligibility

Key inclusion criteria

BMI \geq 40 kg/m² or BMI between 35-40 kg/m² with associated major comorbidities undergoing bariatric surgery

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80 effectively randomized participants: 40 in each group

Key exclusion criteria

The same criteria established by hospital protocol for patients undergoing bariatric surgery

Date of first enrolment

01/03/2015

Date of final enrolment

31/07/2017

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Universitari Sant Joan de Reus

Avinguda Dr Josep Laporte, 2

Reus (Tarragona)

Spain

43204

Sponsor information

Organisation

Hospital Universitari Sant Joan de Reus

Sponsor details

Avinguda Dr Josep Laporte, 2
Reus (Tarragona)
Spain
43204

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/04f7pyb58>

Funder(s)

Funder type

Industry

Funder Name

Nestle S.A.

Results and Publications

Publication and dissemination plan

The protocol and statistical plan are not available. Planned publication of the results in a high-impact peer reviewed journal.

Intention to publish date

31/07/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | 29/08/2018 | 30/08/2018 | No | No |
| Results article | results | 01/12/2018 | | Yes | No |