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

Submission date 19/02/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/02/2018	**Overall study status** Completed	
Last Edited 30/08/2018	**Condition category** Surgery	

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 preoperatory 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 ≥ 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