ISRCTN12131308 https://doi.org/10.1186/ISRCTN12131308

Changes in gastrointestinal hormones after bariatric surgery

Submission date
27/01/2016

Recruitment status
No longer recruiting

Registration date
01/02/2016

Overall study status
Completed

Last Edited
01/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a growing problem worldwide. In Spain, around 22.9% of the population is overweight, with 1.8% being dangerously so (morbid obesity). It is well known that obesity can lead to a number of other serious health conditions such as cancer, cardiovascular disease (disease of the heart and blood vessels) and diabetes. By losing excess weight, it is thought that people can dramatically reduce their risk of developing these conditions. Weight loss surgery, also called bariatric surgery, is a drastic measure used to help people who are dangerously overweight and unable to lose weight naturally (through diet and exercise). There are a number of different types of bariatric surgery; however they all work by limiting the amount a person can eat or reducing the number of calories that are absorbed from food. Recent studies have shown that when a person undergoes bariatric surgery, the amounts of different hormones involved in digestion and regulating fat storage change. The specific changes are also thought to be different depending on what type of bariatric surgery is used. This study will look at three different bariatic surgery procedures: gastric bypass surgery (where the stomach is stapled, making it smaller so less food can be eaten), sleeve gastrectomy surgery (where part of the stomach is removed, making the overall size of the stomach smaller) and a procedure called biliopancreatic diversion with duodenal switch (where a large part of the stomach is removed and what remains is connected to the final segment of the small intestine, so food in the intestine has less time to be absorbed). The aim of this study is to compare levels of hormones after eating in adult patients who have had one of these three bariatric surgery procedures, and compare these levels to those of healthy adults with normal weights.

Who can participate?
Adults who have been morbidly obese for at least 5 years and are having bariatric surgery, as well as healthy adults of the same age with a normal weight.

What does the study involve?
At the start of the study, 50 participants due to have bariatric surgery (gastric bypass surgery, sleeve gastrectomy surgery or biliopancreatic diversion with duodenal switch) and 20 healthy participants of a normal weight attend a study visit. At this visit, they are weighted and measured and have a series of blood tests before and 30, 60, 90 and 120 minutes after eating a standard meal so that their hormone levels can be measured. The hormone test is then repeated

one year later. For the obese patients, weight is measured at these study visits and again 3 and 5 years after surgery.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants taking part in the study.

Where is the study run from?
San Carlos Clinical Hospital (Spain)

When is the study starting and how long is it expected to run for?
February 2008 to May 2015

Who is funding the study?
1. Biomedical Research foundation of Mutua Madrileña (Spain)
2. Metabolic Studies Foundation, Hospial Clinico San Carlos (Spain)
3. Research in Metabolic and Nutrition Foundation (Spain)

Who is the main contact?
Mrs Patricia Martin

Contact information

Type(s)
Scientific

Contact name
Mrs Patricia Martin

Contact details
Servicio de Endocrinologia y Nutrición
Hospital Universitario la Paz
Paseo de la Castellana 261
MADRID
Spain
28046

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Changes in gastrointestinal hormones and its relation with weight loss after gastric bypass, biliopancreatic deviation with duodenal swicht and sleeve gastrectomy: An observational study

Study objectives

The aim of this study is to find out whether the physiological hormonal response after a meal test is different in obese and normal weight patients, and whether bariatric surgery can elicit changes in hormonal responses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hospital Clínico San Carlos, 24/02/2003, ref: B-03/061

Study design
Prospective single-centre case-control study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Morbid obesity

Interventions
Morbidity obese patients who are having Roux-en-Y gastric bypass, biliopancreatic deviations with duodenal switch or sleeve gastrectomy are included in the study.

Obese and control group have anthropometric and hormonal measurements taken at baseline and 1 year after surgery. At each visit, participants have a blood sample taken, which is repeated 0, 60, 90 and 120 minutes after ingestion of a standard test meal.

Obese patients are asked to attend two additional study visits 3 and 5 years after surgery for weight control.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Hormonal response after meal test is measured from blood samples taken at baseline, 30, 60, 90 and 120 minutes after ingestion of a standard test meal, at baseline and one year post surgery.

Key secondary outcome(s))
Weight loss and the height was measured using an electric scale (SECA®) at baseline, 1, 3 and 5 years.

Completion date
31/05/2015

Eligibility

Key inclusion criteria
Obese participant inclusion criteria:
1. Aged between 18 and 65 years
2. BMI ≥ 40 kg/m2 or ≥ 35 kg/m2 with associated major comorbidities likely to improve after weight loss
3. That morbid obesity is set for at least 5 years.
4. Continuing failures to properly supervised conservative treatments
5. Ability to understand the mechanisms by which weight is lost with surgery and understand that good results are not always achieved
6. Understand that the goal of surgery is not reach the ideal weight
7. Commitment to adhere to the rules of follow-up after surgery
8. Informed consent after receiving all the (oral and written) information

Control participant inclusion criteria:
1. Aged between 18 and 65 years
2. No diabetes mellitus (basal glucose <126 mg/dl and/or Hba1c < 6.5%)
3. BMI <30 and >18 kg/m2
4. No drugs or alcohol abuse.
5. No mayor psychiatric disorders (schizophrenia, psychosis) no eating disorders(anorexia nervosa, bulimia)
6. Informed consent after receiving all the (oral and written) information

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Endocrine disorders that can cause morbid obesity.
2. Psychological instability including abuse of alcohol or drugs, major psychiatric disorders (schizophrenia, psychosis), mental retardation, eating disorders (bulimia nervosa, binge eating)
3. Pregnancy

Date of first enrolment
01/02/2008

Date of final enrolment
30/11/2010

Locations

Countries of recruitment
Spain

Study participating centre
Clinico San Carlos Hospital (Hospital Clínico San Carlos)
Calle del Prof Martín Lagos
Madrid
Spain
28040

Sponsor information

Organisation
San Carlos Clinical Hospital (Hospital Clínico San Carlos)

ROR
https://ror.org/04d0ybj29

Funder(s)

Funder type
Not defined

Funder Name
Biomedical Research foundation of Mutua Madrileña

Funder Name
Metabolic Studies Foundation, Hospial Clinico San Carlos

Funder Name
Research in Metabolic and Nutrition Foundation (FINUMET)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available