

Changes in gastrointestinal hormones after bariatric surgery

Submission date 27/01/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/02/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 bariatric 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, Hospital 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Changes in gastrointestinal hormones and its relation with weight loss after gastric bypass, biliopancreatic deviation with duodenal switch 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

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Morbid obesity

Interventions

Morbidly 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 measure

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.

Secondary outcome measures

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

Overall study start date

01/02/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

A total of 23 patients underwent GB surgery, 17 BPD-DS and 10 SG with a control group of 20 healthy and normal weight volunteers

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)

Sponsor details

Endocrinology and Nutrition Service (Servicio de Endocrinología y Nutrición)

Calle del Prof Martín Lagos

Madrid

Spain

28040

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

1. Presented as Patricia Martin's PhD project
2. Planned publication in peer reviewed journals

Intention to publish date

31/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available