ISRCTN57114193 https://doi.org/10.1186/ISRCTN57114193

Gastrointestinal hormones and genes associated to type 2 diabetes remission in non-morbid obesity after bariatric surgery

Submission date
21/03/2013

Recruitment status
No longer recruiting

Registration date
03/05/2013

Overall study status
Completed

Last Edited
22/05/2013

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
Bariatric surgery (weight loss surgery) improves and resolves Type 2 Diabetes (T2D) by several weight-loss-independent mechanisms. Secretion of gastrointestinal hormones may contribute to this. The objective of this study is to analyze the changes in gastrointestinal hormones of less obese patients [Body mass Index (BMI) < 40 kg/m2], after two different surgery techniques. It also analyzes genetic variations (genetic polymorphisms) involved.

Who can participate?
Men and women, aged 30-65, with T2D and BMI 30-40 kg/m2.

What does the study involve?
Patients will be randomly allocated to one of two groups to undergo either gastric bypass (RYGB) or sleeve gastrectomy (SG). Both are routinely performed as metabolic surgery techniques. Blood samples will be collected before surgery, at 6 weeks, and at 12-months. Each time, measurements will take place every 30 minutes, for 3 hours, after a fixed liquid meal. Several hormone tests will be performed.

What are the possible benefits and risks to participants?
Benefits are improvement of obesity and associated problems. Risks are those of a surgical intervention.

Where is the study run from?
In two renowned bariatric surgery reference centres: Hospital Clinico San Carlos, Madrid, Spain, and Hospital Oswaldo Cruz, Sao Paulo, Brazil

When is the study starting and how long is it expected to run for?
Recruitment started on January 2013 and will continue for a period of 20 months. Participants will take part in the study for one year. However, they will be followed up for longer period.

Who is funding the study?
Funding has been provided by the Fundación Mutua Madrileña de Investigación Biomédica.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Fundación Mutua Madrileña de Investigación Biomédica AP 89592011

Study information

Scientific Title
Role of gastrointestinal hormones and genes associated to type 2 diabetes remission in non-morbid obesity after bariatric surgery. A multicentric, randomized trial using different bariatric techniques.

Study objectives
T2D long-term remission differs between bariatric procedures, beyond the effect of weight loss and the GLP-1 response. In restrictive techniques, weight loss is still the main mechanism involved, but in bypassed procedures, liberation of other related hormones may contribute to the action of GLP-1. In RYGB, both mechanisms may coexist. Evaluation of T2D patients with only grade 1 obesity should minimize the influence of weight on the evaluation of these hormonal changes.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The ethics committee of the Hospital Clinico San Carlos approved the study on 21st September 2011 (reference number CI-11/080-E)

Study design
Three-year open randomized prospective trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
Type 2 diabetes

Interventions
Eligible patients with T2D and grade 1 obesity will be randomized to undergo either gastric bypass (RYGB) (performed laparoscopically, with a 150 cm-alimentary limb and a 100-cm-biliopancreatic limb) or sleeve gastrectomy (SG) (also performed laparoscopically, following standardized technique and a 14-Fr bougie)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Remission of type 2 diabetes after metabolic surgery, defined as two categories: complete remission (fasting glucose < 100 mg/dl, normal HbA1c values) and partial remission (fasting glucose 100-125 mg/dl, HbA1c < 6.5%), in both cases in the absence of active pharmacologic treatment, at each time of follow-up (T1 and T2)

Secondary outcome measures
1. Changes in gastrointestinal hormones (ghrelin, insulin, glucagon, GIP, GLP-1, PYY3-36, oxyntomodulin, adiponectin, leptin and GLP-2) using values of area under the curve (AUC), for each bariatric procedure and comparison with a matched control group
2. Analysis of polymorphisms involved in type 2 diabetes and incretin metabolism

Overall study start date
02/01/2013

Completion date
31/08/2014

Eligibility

Key inclusion criteria
1. Men and women
2. Ages 35-60
3. Type 2 diabetes diagnosed 1-10 years prior to recruitment
4. Body mass index (BMI) 30-40 kg/m2
5. C-peptide level > 1 ng/dL
6. Signed written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
It is estimated that a minimum of 30 patients for each type of surgery which means a total of 60 participants, over a 20-month period

Key exclusion criteria
1. HbA1c levels > 6.5% or > 10% at the time of recruitment
2. Creatinine levels > 1.5 mg/dL
3. Ongoing pregnancy, either at the time of recruitment or follow-up
4. Renal failure (ClCr < 50 mL/min)
5. Liver disease
6. Psychiatric disorders

Date of first enrolment
02/01/2013

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Spain

Study participating centre
Department of Endocrinology and Nutrition
Madrid
Spain
28040

Sponsor information

Organisation
Fundación Mutua Madrileña (Spain)

Sponsor details
Fortuny 18
Madrid
Spain
28010

Sponsor type
Government

Website
http://www.fundacionmutua.es

ROR
https://ror.org/00skv9577

Funder(s)

Funder type
Research organisation

Funder Name
Fundación Mutua Madrileña de Investigación Biomédica (Spain) AP 89592011

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration