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Diabetes remission after metabolic gastric bypass, sleeve gastrectomy and greater curvature plication

Submission date
08/11/2015

Recruitment status
No longer recruiting

Registration date
25/01/2016

Overall study status
Completed

Last Edited
15/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Once of the main reasons why people develop T2DM is because they are overweight or obese. Weight loss surgery, also called bariatric surgery, is a drastic measure used to help people who are dangerously overweight. 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 following weight loss can lead to an improvement in the diabetes symptoms. In many people, once they have lost the excess weight, their diabetes improves. The aim of this study is to compare the effects of three different types of weight loss surgery to find out if losing weight following surgery has an effect on diabetes.

Who can participate?
Obese adults between 18 and 60 years, who have type 2 diabetes mellitus (T2DM).

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group undergo the metabolic gastric bypass procedure. This is where the stomach is stapled, making it smaller and the small intestine is made shorter. Participants in the second group undergo a sleeve gastrectomy procedure. This is where part of the stomach is removed, making the overall size of the stomach smaller. Participants in the third group undergo a gastric plication procedure. This is where folds are "sewn" into the stomach, which limits the amount of food that can be eaten at one time. At the start of the study and then again 1, 3 and 12 months after surgery, the weight and body fat of participants in all groups is measured at clinic visits. Blood sugar and other markers of diabetes are also measured at these times, to find out if the surgery has had an influence on their diabetes.

What are the possible benefits and risks of participating?
Participants of the study will benefit from shorter waiting times until they are able to receive their bariatric surgery. They will also be closely followed-up by the research team which measures that any problems would be quickly spotted. Risks of participating include the general risks associated with major surgery. Participants who receive the gastric bypass may also have a greater risk of leaking, bleeding and nutritional deficiencies (not getting enough vitamins and minerals in the diet as they are unable to eat as much).

Where is the study run from?
Bellvitge's University Hospital (Spain)

When is the study starting and how long is it expected to run for?
May 2012 to February 2014

Who is funding the study?
Bellvitge Institute for Biomedical Research (Spain)

Who is the main contact?
Dr Tsung-Hui Hu

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PI11/01960

Study information

Scientific Title
Prognostic factors and pathophysiology of type 2 diabetes mellitus remission following bariatric surgery. gastric bypass, sleeve gastrectomy and greater curvature plication: A randomised controlled trial

Acronym

DIABETCIR

Study objectives
A higher increase in GLP-1 after metabolic gastric bypass compared to sleeve gastrectomy and greater curvature plication will be associated to a greater metabolic improvement in the short (1 month) and mid- term (12 months) after this surgery for the same amount of weight loss achieved. Patients with higher concentrations of GLP-1 receptors in adipose tissue will have a greater metabolic improvement after surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellvitge's Clinical Research and Ethics Committee from Barcelona, 26/01/2012, ref: PI11/01960

Study design
Single-centre non-blinded randomised parallel trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Morbid Obesity and Type 2 Diabetes Mellitus improvement after bariatric surgery

Interventions
Patients are randomly assigned (1:1:1) to three groups using envelope stratification according to the presence of an initial hba1c > or < 7%.

Group 1: Participants undergo a metabolic gastric bypass, a mixed bariatric technique (restrictive pouch and a biliopancreatic limb length of 200cm and alimentary limb of 100cm)
Group 2: Participants undergo a sleeve gastrectomy, a restrictive technique performed over a 36Fr bougie
Group 3: Participants undergo gastric plication, a restrictive technique without gastrectomy and no bowel derivation. It is a greater gastric curvature invagination with two running non absorbable suture, over a 36Fr bougie.

The same surgeon performs all the procedures by laparoscopy. Study participants attend visits at baseline and 1, 3 and 12 months after the three surgical techniques. Postoperative diet progression and medical follow-up is the same for all patients. At each visit, anthropometric and biochemical parameters including glucose, HbA1c, and lipid profile are determined. A study of body composition with DEXA is conducted at baseline and at 12 months after surgery. A standard meal test for determination of plasma GLP-1, glucagon, PYY, ghrelin, insulin and glucose is performed at baseline and at 1 and 12 months after surgery. During the intervention a sample of visceral and subcutaneous adipose tissue is collected.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. GLP-1, glucagon, PYY, Ghrelin, glucose and insulin changes measured using a standard meal test at baseline, 1, 3 and 12 months
2. Weight changes are measured using anthropometric techniques at baseline, 1, 3 and 12 months
3. Body fat changes are measured using Dual-energy X-ray absorptiometry (DEXA) at baseline and 12 months
4. Presence of GLP-1 receptors in adipose tissue is measured from a sample of visceral and subcutaneous adipose tissue at baseline

Key secondary outcome(s))
1. Rate of total, partial and non- T2DM remission is measured using Buse criteria at 12 months
2. Blood pressure changes are measured using a sphygmomanometer at baseline and 12 months
3. Plasma total cholesterol, HDL and triglycerides changes are measured from blood samples at baseline and 12 months
4. Quality of life is measured using the Moorehead-Ardelt II test at 12 months

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Aged between 18 and 60 years
2. BMI of 35-42Kg/m2
3. Diagnosis of type 2 diabetes mellitus (T2DM)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Type 1 diabetes
2. Diabetes secondary to pancreatic injury or other disease (Cushing's syndrome or acromegaly)
3. Presence of GAD auto-antibodies
4. Acute metabolic complications (ketosis, ketoacidosis or hyperosmolar state over the last six

months)
5. Serious infection that can affect blood glucose control during the 4 weeks prior inclusion
6. Cardiovascular events (heart failure, angina pectoris, myocardial infarction or stroke) within 6 months prior to inclusion
7. History of liver disease (chronic active hepatitis or cirrhosis) and/or abnormal liver function (ALT and/or AST 3 times above the upper normal value)
8. Altered renal function (creatinine >1.4 mg/dl in women and 1.5 mg/dl in men)
9. Patients with anticoagulant therapy
10. Congenital or acquired abnormalities of the digestive tract (atresia, stenosis)
11. Pregnancy, nursing or desired pregnancy in the 12 months following the inclusion
12. Recent history of neoplasm (<5 years) except basal cell skin cancer
13. Glucocorticoid use by oral or intravenous route for more than 14 consecutive days in the last three months prior to inclusion
14. Alcoholism, drug addiction or major psychiatric disorder
15. Patient refusal to participate in the study

Date of first enrolment
10/05/2012

Date of final enrolment
28/02/2014

Locations

Countries of recruitment
Spain

Study participating centre
Bellvitge's University Hospital
Feixa Llarga n/n
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Sponsor information

Organisation
Bellvitge Institute for Biomedical Research (IDIBELL)

ROR
https://ror.org/0008xqs48

Funder(s)

Funder type
University/education

Funder Name
Bellvitge Institute for Biomedical Research (IDIBELL)

Results and Publications

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?
Results article	results	01/10/2019	01/07/2020	Yes	No
Results article		01/10/2020	01/06/2021	Yes	No
Results article		11/06/2020	15/02/2023	Yes	No
Results article		18/04/2019	15/02/2023	Yes	No