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Bariatric surgery and type 1 diabetes mellitus

Submission date
02/04/2016

Recruitment status
No longer recruiting

Registration date
12/04/2016

Overall study status
Completed

Last Edited
30/11/2020

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
Diabetes is a condition that causes a person's blood sugar level to become too high. Insulin is the hormone made by beta-cells in the pancreas and controls the amount of glucose in the blood. Type 1 diabetes occurs when the pancreas does not produce any insulin. Type 2 diabetes occurs when the pancreas does not produce enough insulin or the person's cells do not react to insulin. In recent years, the number of patients with type 1 diabetes that are also obese (very overweight) has increased, affecting around 28% of adults and children with type 1 diabetes. The effect of weight loss (bariatric) surgery on type 1 diabetes have only been investigated in small groups of people over a short period of time. Most of the studies that have taken place show that the patients lost weight and didn't have to take so much insulin. They also become less at risk of developing cardiovascular (for example, heart) disease and had improved blood sugar and cholesterol levels in the short term. This study investigates what the long-term effects of bariatric surgery are on obese type 1 diabetics, focussing on blood sugar control, blood pressure and cholesterol levels over time and possible diabetic complications, such as kidney and eye damage. The results are then compared to those taken from a group of obese patients with type 2 diabetes that have also had bariatric surgery.

Who can participate?
Patients with type 1 or 2 diabetes that have undergone bariatric surgery as a treatment for obesity.

What does the study involve?
Health data for type 1 diabetes patients that have had bariatric surgery as a treatment for obesity are compared against type 2 diabetes patients that have had the same procedure. Detailed clinical and biochemical data is collected from medical charts. Information on how long the patient has had diabetes, their insulin requirements and how this changes after the surgery and whether they develop any complications as a result of their diabetes are all assessed, as well laboratory tests to check for metabolic control changes and body fat (lipid profile) changes.

What are the possible benefits and risks of participating?
Participants in the study will benefit from a closer follow-up by the research team. No health risks will be associated with the participation in the study.

Where is the study run from?
A total of eight hospitals in Spain

When is the study starting and how long is it expected to run for?
December 2013 to December 2015

Who is funding the study?
Spanish Society of Endocrinology and Nutrition

Who is the main contact?
1. Dr Nuria Vilarrasa (scientific)
2. Dr Miguel Angel Rubio (scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Nuria Vilarrasa

ORCID ID
http://orcid.org/0000-0003-3188-1990

Contact details
Feixa Llarga s/n
L´Hospitalet de Llobregat (Barcelona)
Spain
08907

Type(s)
Scientific

Contact name
Dr Miguel Angel Rubio

Contact details
Martín Lagos s/n
Madrid
Spain
28040

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PR198/14

Study information

Scientific Title
Long-term outcomes in morbidly obese type 1 diabetic patients undergoing bariatric surgery

Study objectives
Bariatric surgery in T1DM (type 1 diabetes mellitus) provides the benefits of weight reduction on insulin requirements, obesity comorbidities, and some benefits in diabetes complications, but has no effect on the metabolic control in the long-term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bellvitge´s Clinical Research and Ethics Commitee from Barcelona, 14/11/2013, ref :PR198/14

Study design
Multicenter, retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
1. Morbid obesity
2. Type 1 and type 2 diabetes mellitus

Interventions
Systematic review of cases with T1DM who had undergone bariatric surgery. Detailed clinical and biochemical data were retrospectively collected by reviewing the medical charts. Patients were compared with a cohort of T2DM (type 2 diabetes mellitus) with insulin treatment before surgery and matched for initial BMI and HbA1c with T1DM group in a proportion 2:1.
Data collected in the questionnaire included the demographic and anthropometric characteristics of the patients and data regarding type 1 and type 2 diabetes (presentation of diabetes onset, diabetes duration before surgery, basal and prandial insulin bolus requirements

and changes after surgery, use of subcutaneous insulin infusion (ISCII), presence of diabetes complications and the modifications in the use of lipid-lowering or antihypertensive medications). Laboratory tests including glycosylated hemoglobin (HbA1c) and lipid profile . In T1DM, data on retinal photographs and urinary albumin excretion were evaluated. Moreover, acute diabetic complications after surgery were collected. All data were collected before surgery and annually thereafter.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Metabolic control changes, measured using HbA1c values at 1,2,3,4 and 5 years after bariatric surgery in morbidly obese type 1 DM patients. Comparison with HbA1c values in morbidly obese Type 2 DM patients with the same follow-up
2. Anthropometric changes using weight and total weight loss percentage at 1,2,3,4 and 5 years after bariatric surgery in morbidly obese type 1 DM patients. Comparison with weight changes in morbidly obese Type 2 DM patients with the same follow-up
3. Changes in insulin requirements measured using insulin dose (UI/kg body weight) at 1,2,3,4 and 5 years after bariatric surgery in morbidly obese type 1 DM patients. Comparison with insulin dose (UI/kg body weight) in morbidly obese Type 2 DM patients with the same follow-up

Secondary outcome measures
1. Changes in hypertension prevalence measured using percentage of patients with hypertension treatment at 5 years after bariatric surgery in T1DM and T2DM
2. Changes in dyslipidemia prevalence measured using percentage of patients with dyslipidemia treatment at 5 years after bariatric surgery in T1DM and T2DM
3. Changes in obstructive sleep apnea prevalence measured using percentage of patients with obstructive sleep apnea treatment at 5 years after bariatric surgery in T1DM and T2DM
4. Changes in diabetic microvascular complications measured using urinary albumin excretion rate in 24 h urine and retinal photographs in type 1 DM patients at 1,2,3, 4 and 5 years after bariatric surgery
5. Prevalence of diabetic acute complications in Type 1 DM measured using percentage of patients with severe hypoglycemic episodes, ketosis and ketoacidosis at 1,2,3,4,5 years after surgery
6. Differences in metabolic and weight outcomes among bariatric techniques measured using HbA1c, weight and insulin dose reduction at 12 months in type 1 DM according to the type of bariatric procedure undergone

Overall study start date
01/12/2013

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Patients with T1DM according to ADA criteria, with biochemical data available with a minimum follow-up after surgery of 12 months after bariatric surgery
2. Patients with T2DM with insulin treatment before surgery and matched for initial BMI and HbA1c with T1DM group in a proportion 2:1

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 in type 1 diabetes group and 60 in type 2 diabetes group

Key exclusion criteria
1. Diabetes secondary to pancreatic injury or other disease (Cushing´s syndrome or acromegaly)
2. Follow- up < 12 months after bariatric surgery
3. Absence of biochemical data available (HbA1c) before and/or 12 months after surgery
4. Patient refusal to participate in the study

Date of first enrolment
01/12/2013

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Spain

Study participating centre
Bellvitge´s University Hospital
Feixa LLarga s/n
Barcelona
Spain
08907

Study participating centre
Hospital Clínico San Carlos. IDISSC.
Martín Lagos s/n
Madrid
Spain
28040

Study participating centre

Sabadell University Hospital (UAB)
Corporació Sanitària Parc Taulí
c/ Parc Taulí nº 1
Sabadell
Spain
08208

Study participating centre
Hospital de la Santa Creu i Sant Pau
C/Sant Antoni Maria Claret 167
Barcelona
Spain
08025

Study participating centre
Hospital Vall d´Hebron
Passeig Vall d'Hebron, 119-129
Barcelona
Spain
08035

Study participating centre
Hospital Universitario Virgen del Rocío
Avenida Manuel Siurot s/n
Sevilla, Spain
Spain
41013

Study participating centre
Hospital Universitari Arnau de Vilanova
Avda. Rovira Roure 80
25198 Lleida
Spain
25198

Study participating centre
Hospital Clinic Universitari
c/ Villaroel 170
Barcelona
Spain
08036

Sponsor information

Organisation
Spanish Society of Endocrinology and Nutrition (SEEN)

Sponsor details
c/Villalar 7 bajo-interior derecha
Madrid
Spain
28001
914313294
secretaria@seen.es

Sponsor type
Research organisation

Website
www.seen.es

ROR
https://ror.org/01tk4y529

Funder(s)

Funder type
Research organisation

Funder Name
Spanish Society of Endocrinology and Nutrition

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed scientific journals.

Intention to publish date
01/05/2016

Individual participant data (IPD) sharing plan

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	01/04/2017	30/11/2020	Yes	No