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Study of laparoscopic biliopancreatic diversion modality for treatment of type 2 diabetes in patients with a BMI between 30 and 35. [Estudio y resultados de una modalidad de derivación biliopancreática laparoscópica para el tratamiento de la diabetes tipo 2 en pacientes con IMC entre 30 y 35]

Submission date
23/01/2012

Recruitment status
No longer recruiting

Registration date
20/02/2012

Overall study status
Completed

Last Edited
31/07/2014

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
Type 2 diabetes is an illness in which the body does not produce or respond correctly to insulin, an important hormone that transforms glucose into the energy that the body needs to work. People with diabetes are prone to suffer other illnesses and this makes its forecast worse. Type 2 diabetes affects over 5% of adults in the world (250 million people). It is estimated that by 2025 this will have doubled. Medical treatment cant cure diabetes. However, bariatric surgery cures diabetes in morbidly obese patients and this is not related to weight loss, so it would cure diabetes in non morbidly obese patients. It is observed that glucose tolerance improved in diabetic patient after a gastrectomy and the immediacy of that improvement appeared to be due to the involvement of hormones that control insulin secretion. This showed that the diabetes cure was linked to hormone alterations in the small intestine because of the food transit variation, stimulating insulin secretion in the pancreas. The aim of this study is to assess the effects of a surgical treatment consisting of a stomach reduction and a biliopancreatic bypass that redirects the food to avoid the first section of the intestine and go directly to the last part. This act stimulates natural insulin secretion.

Who can participate?
Patients aged between 18 and 60 with type 2 diabetes.

What does the study involve?
Participants will be randomly allocated into one of two groups. One group will receive the surgical treatment described above and the other group will receive the standard drug treatment for diabetes.

What are the possible benefits and risks of participating?
There could be adverse events related to the surgery (chance of death below 2%, serious complications in around 7% and minor complications in around 17%) and also a reduction of the vitamins absorbed in the digestion that could be solved by taking vitamin supplements.

Where is the study run from?
Royo Vilanova Hospital (Spain).

When is study starting and how long is it expected to run for?
The study started in February 2012 and will finish 14 months later.

Who is funding the study?
Aragon Institute of Health Sciences (Spain).

Who is the main contact?
José Antonio Fatás Cabeza

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI10/02340

Study information

Scientific Title
Study and results of a laparoscopic biliopancreatic diversion modality for diabetes type 2 treatment in patients with a BMI between 30 and 35: a randomized prospective clinical trial

Study objectives
The minimally invasive surgical technique proposed by the research team prevents the passage of food into the duodenum and causes an early filling of the ileum, triggering an enzymatic cascade that stimulates an autologous secretion of insulin in patients with pancreatic reserve.

This surgical technique results in the cure of type 2 diabetes (defined by the Diabetes American Association as a fasting glucose less than 100 mg/dl in venous plasma, a glycemia at 2 hours after an oral glucose overload with 75 g less than 140 mg/dl and HbA1c less than 6.5% and normal insulin levels in blood) without causing malnutritional states and maintaining the BMI between normal values and overweight and improving quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Clinical Research Ethics Committee of Aragon [Comité Ético de Investigación Clínica de Aragón (CEICA)], 16/03/2011, ref: C.I.EC10/028

Study design
Prospective randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Type 2 diabetes

Interventions
A five trocars laparoscopic surgical intervention, a gastric cross-section leaving a 300 ml gastric reservoir, a biliopancreatic derivation with a jejunoileal anastomosis at 120 cm from the ileocecal valve and a jejunal section at 320 cm from the ileocecal valve.

The pharmacological treatment for the control group will be the usual one used in clinical practice for the control of type 2 diabetic patients. This treatment includes antidiabetics and/or insulin.

The drug type, dose and administration frequency depends on the patient and its characteristics. The more common antidiabetic treatments include the following ones: gliclazide, glimepiride, repaglinide, metformin, pioglitazone, rosiglitazone, sitagliptine, vildagliptine and exenatide.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Normal glucose levels
2. Insulin blood level
3. Normal nutritional state assessed against calcium, iron, protein and vitamin metabolism
4. BMI between 20 and 30
5. Quality of life

Secondary outcome measures
1. Insulin production related hormones evolution (GIP, GLP1, ghrelin, neuropeptide YY)
2. Glucose metabolism (glucagon test, basal proinsulin)

Overall study start date
01/02/2012

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Patients diagnosed with type 2 diabetes
2. Between 18 and 60 years old
3. Body mass index (BMI) between 30 and 35
4. Less than 10 years of illness evolution
5. Subject to medical treatment (oral antidiabetics, and/or insulin) and without enough control
6. More than 2 years of medical treatment and adequate pancreatic reserve (haemoglobin glycosylated determination with a result of more than 7)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
74

Key exclusion criteria
1. Positive anti glutamic acid decarboxylase (GAD) antibodies
2. Patients diagnosed with type 2 diabetes controlled with one or two oral antidiabetics, preanesthetic evaluation between 4 or 5 Anesthetic Society of America criteria values (ASA)
3. Laparoscopic and surgery general contraindications

Date of first enrolment
01/02/2012

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Spain

Study participating centre
Servicio de Cirugía General y del Aparato Digestivo
Zaragoza
Spain
50015

Sponsor information

Organisation
Aragon Institute of Health Sciences [Instituto Aragonés de Ciencias de la Salud] (Spain)

Sponsor details
Avenida Gómez Laguna 25
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50009

Sponsor type
Research organisation

Website

http://www.ics.aragon.es/

ROR
https://ror.org/05p0enq35

Funder(s)

Funder type
Research organisation

Funder Name
Aragon Institute of Health Sciences [Instituto Aragonés de Ciencias de la Salud] (Spain)

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