

# 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]

<b>Submission date</b> 23/01/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 31/07/2014	<b>Condition category</b> 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

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**

Dr José Antonio Fatás Cabeza

**Contact details**

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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

Planta 3

Zaragoza

Spain

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