

Loop Duodeno-Jejunal Bypass with Sleeve Gastrectomy for type 2 diabetes mellitus in low BMI patients

Submission date 05/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/11/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/11/2012	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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 mellitus (T2DM) is a disease with high mortality rates. It is the most common endocrine disorder worldwide. People with diabetes are at increased risk of cardiovascular diseases. The current treatment includes diet control, exercise, and use of anti-diabetic medications. However, recent evidence suggests surgery can reduce the symptoms of T2DM, especially in morbidly obese patients. The aim of our study is to evaluate the effectiveness and safety of Loop Duodeno-Jejunal Bypass surgery in T2DM patients.

Who can participate?

Either male or female patients aged 18 - 65 years, with a Body Mass Index (BMI) of less than 35 kg/m². Participants should also have been diagnosed with T2DM for at least 6 months.

What does the study involve?

Loop Duodeno-Jejunal Bypass surgery.

What are the possible benefits and risks of participating?

Patients may experience reduced symptoms of T2DM, however there is the risk that there may be complications from the surgery.

Where is the study run from?

EDa Hospital, Taiwan

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

The study started in October 2011 and will end in September 2013.

Who is funding the study?

EDa Hospital, Taiwan

Who is the main contact?
Professor Chih-Kun Huang
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Study information

Scientific Title
Loop Duodeno-Jejunal Bypass with Sleeve Gastrectomy for type 2 diabetes mellitus in low BMI patients: early results

Acronym
LD-JB SG

Study objectives
To study the safety and efficacy of Loop Duodeno-Jejunal Bypass with sleeve gastrectomy for type 2 diabetes mellitus (T2DM) in low body mass index (BMI) patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Surgery: Loop Duodeno-jejunal bypass with sleeve gastrectomy.

There is only one study arm which is surgery: Loop duodeno-jejunal bypass with sleeve gastrectomy which will be done for consenting patients who fulfill the inclusion criteria.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Patients will be divided into four groups on the basis of their postsurgical status:

1. Those in remission of T2DM, defined by HbA1c < 6.5% without oral hypoglycemic drugs or insulin
2. Those with glycemic control, defined as HbA1C of < 7 % despite no use of anti-diabetic medications
3. Those with improvement of their T2DM, defined as a reduction of at least 25% in the fasting plasma glucose level and/ or at least 1% in the pre-operative HbA1c level with hypoglycemic drug treatment
4. Those with failure of surgical procedure, defined as no significant improvement or worsened if a patient required an additional anti-diabetic medication

Key secondary outcome(s)

1. Resolution of co-morbidities
2. Complications related to procedure

Completion date

30/09/2013

Eligibility

Key inclusion criteria

1. Age 18-65 years
2. BMI < 35 kg/m²
3. Poorly controlled T2DM for at least 6 months with glycosylated haemoglobin (Hb A1C) level of >7.0%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Patients younger than 18 or older than 65 years
2. Those planning pregnancy in the next 2 years
3. Type 1 diabetes mellitus (T1DM) patients
4. Latent autoimmune diabetes in adults
5. Malignancy
6. Debilitating disease
7. Unresolved psychiatric illness
8. Substance abuse
9. American Society of Anesthesiologists (ASA) classification > III

Date of first enrolment

01/10/2011

Date of final enrolment

30/09/2013

Locations

Countries of recruitment

Taiwan

Study participating centre

1 E-Da Road

Kaohsiung

Taiwan

82445

Sponsor information

Organisation

E-Da Hospital (Taiwan)

ROR

<https://ror.org/00eh7f421>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

E-Da Hospital (Taiwan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration