

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

<b>Submission date</b> 05/11/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/11/2012	<b>Condition category</b> 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/m<sup>2</sup>. 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**  
Dr Chih-Kun Huang

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## Additional identifiers

**Protocol serial number**  
N/A

## 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/m<sup>2</sup>
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