ISRCTN63241920 https://doi.org/10.1186/ISRCTN63241920

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

Registration date
15/11/2011

Overall study status
Completed

Last Edited
27/11/2012

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 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 meditations. 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 ahve 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?
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Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Prospective study

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