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Laparoscopic band-separated mini-gastric bypass

Submission date
03/01/2016

Recruitment status
No longer recruiting

Registration date
06/01/2016

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
A gastric bypass is a type of weight loss surgery. It involves making the stomach smaller using special surgical staplers. These creates a small pouch which is then connected to a section of the small intestine, therefore bypassing the rest of the stomach and bowel. This results in a person not being able to eat as much food as before and they also absorb fewer calories from the food that they do eat. Modifications have included using a silicone band to restrict the size of the stomach rather than using staplers. This has many advantages, including being able to access the bypassed stomach to treat ulcers, bleeding episodes and cancer; access to the duodenum (first part of the small intestine) and bile ducts; tailored weight loss; reversal of deficiencies in vitamins and nutrients; being able to reverse the entire procedure; reduced risk of gastro-jejunostomy leaks, due to reduced pressure on the anastomosis; and prevention of acute gastric dilatation (abnormal enlargement of the stomach). However, potential disadvantages exist, including erosion of bands in the stomach and small intestine. Adjustable gastric bands with low pressure reduce the probability of band erosion and mini-gastric bypass has been shown to be effective. This study compares loss of weight, changes in other health conditions that the patient may have (co-morbidities, such as diabetes), quality of life, the number of complications and side effects, the degree of complexity of the surgical technique and operating costs of a new laparoscopic band-separated mini- gastric bypass (LBSMGB) procedure compared with the standard stapler (linear cutter) - separated mini-gastric bypass (LSSMGB).

Who can participate?
Obese adult patients with a BMI of between 35 kg/m2 and 60 kg/m2.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo the laparoscopic band-separated mini-gastric bypass procedure. Those in the second group undergo the linear cutter stapler-separated mini-gastric bypass procedure. All patients are then followed up one month after surgery and again after 3, 6 and, finally, 12 months after surgery where weight loss, changes in co-morbidities and quality of life are assessed.

What are the possible benefits and risks of participating?
Participants who undergo receive LSSMGB may be at risk of gastric (stomach) and jejunal (small

intestine) leaks. Participants who receive LBSMGB may be at risk of erosion of bands in the stomach and jejunum.

Where is the study run from?
National Scientific Center for Oncology and Transplantation (Kazakhstan)

When is the study starting and how long is it expected to run for?
July 2015 to January 2017

Who is funding the study?
The Society of Bariatric and Metabolic Surgeons of Kazakhstan

Who is the main contact?
Professor Oral Ospanov

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of laparoscopic band-separated mini-gastric bypass and linear cutter stapler-separated mini-gastric bypass: a randomized controlled trial

Acronym

LBSMGB-RCT

Study objectives
The aim was to compare the reduction of body weight, changes in co-morbidities, quality of life, the number of complications and side effects, the degree of complexity of the surgical technique and operating costs of laparoscopic band-separated mini- gastric bypass with stapler (linear cutter) - separated mini-gastric bypass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Astana Medical University, 17/07/2015, ref: No. 7

Study design
Interventional prospective randomized controlled trial single-centre study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Morbid obesity

Interventions
Participants are randomly allocated have one of two possible surgeries:
1. Laparoscopic band-separated mini-gastric bypass: An adjustable low pressure gastric band was introduced in the abdomen and retracted through the retrogastric tunnel. The front wall of the stomach below the band was displaced in the upward direction through the ring band, increasing the size of the anterior portion of the stomach pouch so that a gastro-entero-anastomosis could be created at this point. Gastro-gastric sutures were placed to create a gastro-gastric plication around the band and hold it in position. The band tubing was exteriorized and connected to a special port, which was secured to the abdominal wall fascia. A jejunal loop was created about 200 cm from the ligament of Treitz and anastomosed to the gastric pouch by hand using Vicryl 2 /0 sutures.
2. Linear cutter stapler-separated mini-gastric bypass: standard surgery

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Weight loss, measured by body weight in kg (BMI – body mass index kg/m 2) and waist circumference before and after surgery and also the percentage of excess weight loss (%EWL) (at 6 months and then 12 months after surgery)
2. Changes in co-morbidities by evaluation of symptoms: diabetes improved or resolved in % of patients, hyperlipidemia improved in %, hypertension improved or resolved in %, and obstructive sleep apnea improved or resolved in % of patients
3. Quality of life, measured by the quality of life questionnaire the Moorehead-Ardelt Quality of Life Questionnaire II

Follow-up for all treatment arms: 1, 3, 6, 12 months after the surgery

Secondary outcome measures
Postoperative morbidity

Overall study start date
17/07/2015

Completion date
22/01/2017

Eligibility

Key inclusion criteria
Obese patients:
1. aged between 18 and 60
2. with American Society of Anesthesiologists (ASA) physical status of I or II
3. BMI ≥ 35

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 60 patients allocated in two groups each consisted of 30 patients.

Total final enrolment
80

Key exclusion criteria
Obese patients with BMI ≥ 60 kg/m2.

Date of first enrolment
20/07/2015

Date of final enrolment
28/10/2016

Locations

Countries of recruitment
Kazakhstan

Study participating centre
National Scientific Center for Oncology and Transplantation
Syganak, 5/1, kv.48
Astana
Kazakhstan
010016

Sponsor information

Organisation
The Society of Bariatric and Metabolic Surgeons of Kazakhstan

Sponsor details
Syganak str.,5/1, kv.48
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Sponsor type
Other

ROR
https://ror.org/050fgea76

Funder(s)

Funder type
Other

Funder Name

Results and Publications

Publication and dissemination plan

1. Publication (in Trials) study protocol (March 2016)
2. Publication (in Obesity Surgery Journal) results of study (January 2017)

Intention to publish date

31/03/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2019	28/05/2020	Yes	No