

# Laparoscopic band-separated mini-gastric bypass

<b>Submission date</b> 03/01/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/05/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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-jejuno-stomy 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/m<sup>2</sup> and 60 kg/m<sup>2</sup>.

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

Prof Oral Ospanov

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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

## **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<sup>2</sup>) 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  $\geq$  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  $\geq$  60 kg/m<sup>2</sup>.

**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

Astana

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010016

**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?
<a href="#">Results article</a>	results	01/12/2019	28/05/2020	Yes	No