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# Laparoscopic Surgery for Severe Obesity combined with gastroesophageal reflux disease

**Submission date**
14/01/2015

**Recruitment status**
No longer recruiting

**Registration date**
28/01/2015

**Overall study status**
Completed

**Last Edited**
27/01/2015

**Condition category**
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Obesity often leads to problems of heartburn (burning sensation in chest) and regurgitation (taste of acid in throat or mouth), which fall under the category of gastroesophageal reflux disease (GERD). The study compares two types of procedures and the aim is to identify if it is possible to treat both obesity and GERD at the same time.

Who can participate?
Adults with severy obesity combined GERD symptoms.

What does the study involve?
Participants are randomly allocated to one of two groups:
Group 1 - laparoscopic great curvature plication (which reduces the stomach by creating an internal fold) and laparoscopic fundoplication (for GERD)
Group 2 - laparoscopic fundoplication only.

What are the possible benefits and risks of participating?
Direct benefit will be healing of heartburn and other symptoms of GERD. Possible side effect is the risk of persistent difficulty in swallowing (called dysphagia).

Where is the study run from?
Single center of Akmola Regional Hospital № 2 (Kazakhstan).

When is the study starting and how long is it expected to run for?
From January 2010 to December 2015

Who is funding the study?
Scientific and Educational Centre for Development of Laparoscopic Surgery in Kazakhstan

Who is the main contact?
Professor Dr.Oral Ospanov
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# 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
Laparoscopic Surgery for Severe Obesity combined with gastroesophageal reflux disease: a pilot single-centre single-blind two-arm randomised controlled study

### Study objectives
1. An elevated body mass index (BMI) frequently results in the development of gastroesophageal reflux disease (GERD) symptoms, amongst which heartburn and regurgitation are the most common complaints,
2. Laparoscopic great curvature plication and laparoscopic fundoplication provide an anti-reflux effect similar to the standard Nissen laparoscopic fundoplication, at the same time significantly surpassing it in terms of bariatric effectiveness.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of the Medical University of Astana 15/01/2010

### Study design
Pilot single-centre single-blind two-arm randomised controlled study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Severe obesity combined with gastroesophageal reflux disease

### Interventions
Laparoscopic fundoplication + great curvature gastric plication compared to "Floppy Nissen" laparoscopic fundoplication

### Intervention Type
Procedure/Surgery

### Primary outcome measure
1. X-ray test performed with barium contrast
2. Esophagogastroscopy before the surgery and 1, 3, 6, 12 and 24 months after the surgery
3. 24hr pH monitoring of the esophagus lower third post-surgery
4. Body weight in kg

### Secondary outcome measures
1. The DeMeester score reflecting pH at gastroesohageal junction, within 1-24 months after the surgery
2. Bariatric effectiveness assessed by excessive weight loss percentage (%EWL)

### Overall study start date
12/01/2010

### Completion date
15/12/2015

## Eligibility

### Key inclusion criteria
1. Male and female adult participants aged over 16
2. Severe obesity combined with gastroesophageal reflux disease: BMI 35 - 39 kg/m2 (obesity class II) and no previous abdominal surgeries in the past.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
114

### Key exclusion criteria
1. The refusal of a patient to have surgery and/or to participate in the ongoing study at any stage of the study
2. Conversion of laparoscopic surgery to open (traditional) surgery
3. Diseases of other organs and systems, the treatment of which could affect the course of reflux disease.
4. BMI less than 30 and more than 39 kg/m2.
5. Presence of a large diaphragmatic hernia
6. The degree of shortening of the esophagus 2
7. Patients who have had surgery in the cardioesophageal area
8. Patients who have had surgery within the abdominal cavity
9. No need for other simultaneous operations

### Date of first enrolment
15/01/2010

### Date of final enrolment
15/12/2014

## Locations

### Countries of recruitment
Kazakhstan

### Study participating centre
**Astana Medical University**
Kazakhstan

## Sponsor information

### Organisation
Scientific and Educational Centre for Development of Laparoscopic Surgery in Kazakhstan

### Sponsor details
Syganak str., 5/1, kv.48
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**Sponsor type**
Charity

# Funder(s)

**Funder type**
Charity

**Funder Name**
Scientific and Educational Centre for Development of Laparoscopic Surgery in Kazakhstan

# Results and Publications

**Publication and dissemination plan**
Calculation of primary data and results of analysis.

**Intention to publish date**
15/03/2015

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Stored in repository