

Laparoscopic Surgery for Severe Obesity combined with gastroesophageal reflux disease

Submission date 14/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/01/2015	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 severe 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

oospanov@icloud.com

Contact information

Type(s)

Scientific

Contact name

Prof Oral Ospanov

Contact details

Syganak str.,5/1, kv.48

Astana (Aqmola)

Kazakhstan

010016

+77015287734

Ospanov.o@amu.kz

Additional identifiers

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

Study type(s)

Treatment

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(s)

1. X-ray test performed with barium contrast
2. Esophagogastrosopy 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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Funder(s)

Funder type

Charity

Funder Name

Scientific and Educational Centre for Development of Laparoscopic Surgery in Kazakhstan

Results and Publications

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

Stored in repository