Laparoscopic Surgery for Severe Obesity combined with gastroesophageal reflux disease

Submission date 14/01/2015	Recruitment status No longer recruiting	 Prospectively registered
		<pre>Protocol</pre>
Registration date 28/01/2015	Overall study status Completed	Statistical analysis plan
		Results
Last Edited 27/01/2015	Condition category Digestive System	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.		
Group 1 - laparosco internal fold) and la	domly allocated to one	ation (which reduces the stomach by creating an ion (for GERD)
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 Single center of Ak	run from? mola Regional Hospital	№ 2 (Kazakhstan).
When is the study starting and how long is it expected to run for?		

Who is funding the study?

From January 2010 to December 2015

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

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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 Astana (Aqmola) Kazakhstan 010016

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