Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2020

Clinical trial of comparing of two methods of measuring the bypassed bowel based on ″total small bowel length" and "Body Mass Index” on benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients

Protocol summary

Summary

The purpose of this study is to compare the efficacy and surgical complications of laparoscopic Mini Gastric Bypass (MGB) in morbidly obese patients between two different methods in terms of measuring the bypass bowel length and body mass index. This study is a double blinded randomized clinical trial (Phase II) which is going to run in Obesity Clinic in Rasoul-e-Akram Hospital between 2017 and 2019. Inclusion criteria are morbid obese patients (BMI higher than 40 or higher than 35 along with comorbidities) and patient aged 18-60 years. Patients with history of previous abdominal or bariatric surgery and patients with a small bowel length shorter than 300 centimeters are excluded. One hundred patients will be enrolled the study and randomized into two groups and follows at 1, 3, 6 and 12 months after surgery. Intervention group is measuring the bypassed bowel based on about one third of total small bowel length and control group is measuring the bypassed bowel based on BMI which is the standard procedure. The examined outcomes are weight loss, complications, comorbidities and malnutrition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612118588N21**
Registration date: **2017-02-12, 1395/11/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Mohadeseh Pishgahroudsari

Name of organization / entity

Mnimally Invasive Surgery Research Center

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing of two methods of measuring the bypassed bowel based on ″total small bowel length" and "Body Mass Index” on benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients

Public title

Comparing of benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients by two methods

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patients with body mass index more than 40 or more than 35 with one obesity commodities.
Exclusion Criteria: Patients with history of previous abdominal or bariatric surgery and the patients with common channel less than 3 meters.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical sciences
Street address
Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.
City
Tehran
Postal code
Approval date
2016-12-28, 1395/10/08
Ethics committee reference number
IR.IUMS.REC 1395.95-03-140-28882

Health conditions studied

1

Description of health condition studied
Morbid obesity
ICD-10 code
E66.8
ICD-10 code description
Morbid obesity

Primary outcomes

1

Description
weight loss
Timepoint
Before the intervention, one month after the intervention, three months after the intervention, six months after intervention, and twelve months after intervention
Method of measurement
scale

2

Description
comorbidities of obesity
Timepoint
Before the intervention , one month after the intervention, three months after the intervention, six months, and 12 months after interventio
Method of measurement
History, Physical Exam, Lab test

3

Description
malnutrition
Timepoint
one month after the intervention, three months after the intervention, six months, and twelve months after intervention
Method of measurement
Lab Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group after measuring the total small bowel length, almost one third of this length will be bypassed.
Category
Treatment - Surgery

2

Description
control group: In this group length of bypassed bowel is measured based on patient's body mass index.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Rasool-e-Akram Hospital

Full name of responsible person
Dr.Seyed Sattar Darabi

Street address
Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice President of Research, Iran University of Medical Sciences

Full name of responsible person
Dr. Seyed Ali Javadmousavi

Street address
Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice President of Research, Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Minimally Invasive Surgery Research Center, Iran University of Medical Sciences

Full name of responsible person
Dr.Seyed Sattar Drabi

Position
Fellowship of Minimally Invasive Surgery

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty