

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of surgical complications and outcomes of gastric bypass and banding in morbid obesity

Protocol summary

Summary

This study is a single blind, randomized clinical trial. The purpose of this study is comparison between complications of two methods of surgery (Gastric Bypass and Banding) in the treatment of morbid obesity in patients who are candidates for surgical treatment in Imam Reza Hospital of Kermanshah. The criteria for inclusion of study are: BMI between 30 to 50; The absence of hiatal hernia; No history of previous surgery. The criteria for exclusion of study are: Immunodeficient patients; Who had a history of steroid use; Patients with a history of mental illness. A total of 290 patients are randomly allocated into two groups surgery (Gastric Bypass and Banding). Both groups will be followed and compared during six month period of time, for complications (Bleeding, Wound Infection, and Hematoma).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013013112322N1**

Registration date: **2013-09-19, 1392/06/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-19, 1392/06/28

Registrant information

Name

Baharak Shahin

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6303

Email address

shahin.baharak@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice-chancellor for Research and Technology

Expected recruitment start date

2013-10-15, 1392/07/23

Expected recruitment end date

2014-03-15, 1392/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of surgical complications and outcomes of gastric bypass and banding in morbid obesity

Public title

Comparative study of surgical complications and outcomes of gastric bypass and banding in morbid obesity

Purpose

Treatment

Inclusion/Exclusion criteria

The criteria for inclusion of study are: BMI between 30 to 50; The absence of hiatal hernia; No history of previous surgery. The criteria for exclusion of study are: Immunodeficient patients; Who had a history of steroid use; Patients with a history of mental illness.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **290**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences. Research Center

Street address

University Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Postal code

6154896587

Approval date

2011-11-26, 1390/09/05

Ethics committee reference number

38630

Health conditions studied

1

Description of health condition studied

Morbid Obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

Primary outcomes

1

Description

Bleeding

Timepoint

At the first week, third and sixth months

Method of measurement

Corresponding to physical examination

Secondary outcomes

1

Description

Hematoma

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

2

Description

Wound Infection

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

Intervention groups

1

Description

Gastric Bypass (In this procedure first divides the stomach into a small upper pouch and a much larger lower "remnant" pouch and then re-arranges the small intestine to connect to both)

Category

Treatment - Surgery

2

Description

Banding (This is a medical procedure which uses elastic bands for constriction)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Kermanshah

Full name of responsible person

Baharak Shahin

Street address

General Surgery Ward, Imam Reza Hospital, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

University Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah university of medical sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Baharak Shahin

Position

Resident of General Surgery

Other areas of specialty/work

Street address

University Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

6158878888

Phone

+98 83 1838 4185

Fax

+98 83 1427 6310

Email

Shahin.baharak@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Khosro Setayeshi

Position

General Surgeon

Other areas of specialty/work

Street address

University Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

6158965478

Phone

+98 83 1838 4185

Fax

+98 83 1839 4920

Email

k.setaishi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Baharak Shahin

Position

Resident of General Surgery

Other areas of specialty/work

Street address

University Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

6158878888

Phone

+98 83 1838 4185

Fax

+98 83 1427 6310

Email

Shahin.baharak@kums.ac.ir

Web page address

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