

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect Of Stapler Line Reinforcement On Complications Of Laparoscopic Sleeve Gastrectomy

Protocol summary

Summary

Effect Of Stapler Line Reinforcement On Complications Of Laparoscopic Sleeve Gastrectomy. Nowadays Laparoscopic Sleeve Gastrectomy (LSG) is utilized more often for management and treatment of morbid obesity. However, Despite having significant benefits, it has potential serious complications. Prevention is the best and cost effective way of controlling these complications although there is controversy among surgeons. Patient will be study with BMI (Body Mass Index) of 40 or more and no history of diabetes mellitus and/or pulmonary Disease. Patient Hypoxia; Hypoalbuminemia will be excluded from study. 100 patients were selected and randomly divided into 2 groups; first group underwent Stapler Line Reinforcement and another group had operation without stapler line reinforcement. We compared the following complications between the two groups: leaking from operation zone, Bleeding and stenosis that need intervention, And if it is worth to spend more time in theater and sedate longer due to stapler line reinforcement. Worth of Longer sedation and operation time due to stapler line reinforcement

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100629181N2**
Registration date: **2016-12-06, 1395/09/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-06, 1395/09/16

Registrant information

Name

Nasser Malekpour Alamdari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 4089

Email address

nassermalekpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Modares clinical development center

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect Of Stapler Line Reinforcement On Complications Of Laparoscopic Sleeve Gastrectomy

Public title

Effect Of Surgical Line Reinforcement On Complications Of Laparoscopic Sleeve Gastrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patient with BMI (Body Mass Index) upon 40
Exclusion Criteria: uncontrolled diabetics, uncontrolled cardiopulmonary disease, untreated psychological condition, hypoxia, hypoalbuminemia.

Age

No age limit
Gender
Both
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
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

Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Avenue, Velenjak, Shahid Beheshti
University of medical Science

City

Tehran

Postal code

Approval date

2016-10-02, 1395/07/11

Ethics committee reference number

IT.SBMU.RETECH.REC.1395.427

Health conditions studied

1

Description of health condition studied

Morbid Obesity

ICD-10 code

E66.8

ICD-10 code description

other obesity

Primary outcomes

1

Description

Decreasing leakage

Timepoint

3th 15th days post operation
Method of measurement
Gastrographin and physical examination

2

Description

Decreasing bleeding

Timepoint

first day after surgery

Method of measurement

Hematocrit and drain output

Secondary outcomes

1

Description

Increasing stenosis

Timepoint

3th day post operation

Method of measurement

Gastrographin study

2

Description

Time consuming

Timepoint

During operation

Method of measurement

Operation time

Intervention groups

1

Description

Intervention: Stapler Line Reinforcement in surgical zone
with suture

Category

Prevention

2

Description

Control: staple line without suture

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modaress Hospital

Full name of responsible person

Nasser Malekpour Alamdari

Street address

Shahid Modares Hospital, Saadat Abad.

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

ShahidBeheshti University of Medical Sciences

Full name of responsible person

Nilofar Massoudi

Street address

ShahidBeheshti University of Medical Sciences, Aarabi Street,Velenjak.

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

ShahidBeheshti 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

ShahidBeheshti University of Medical Sciences

Full name of responsible person

Nasser Malekpour Alamdari

Position

Vascular surgeon Fellowship

Other areas of specialty/work
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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

