

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the Effectiveness of Concomitant Cruroplasty with Sleeve Gastrectomy for Preventing De-novo Gastric Reflux after Sleeve in Patients with Severe Obesity in Comparison to Control Group Who Will Recieve The Only Sleeve Gastrectomy

Protocol summary

Study aim

Evaluating and comparison of the incidence of de-novo GERD and de-novo hiatal hernia after concomitant cruroplasty and sleeve gastrectomy with the sleeve gastrectomy alone. Evaluating and comparison of the mean of GERD-QL Questionnaire score after concomitant cruroplasty and sleeve gastrectomy with sleeve gastrectomy itself.

Design

Single-blinded randomized controlled parallel clinical trial

Settings and conduct

This study is going to be conducted as a single-blinded randomized controlled parallel clinical trial in Isfahan center of excellence for bariatric surgery on patients with severe obesity and otherwise health and evaluate the preventing effects of concomitant cruroplasty with sleeve gastrectomy on postoperative gastric reflux

Participants/Inclusion and exclusion criteria

Patient with severe obesity who are a candidate for bariatric surgery without any sign and symptoms for gastric reflux without any history of it and with consuming no PPIs drugs, and without any clinical evidence of GERD and hiatal hernia in endoscopy who are willing to participate in this study and will complete all the postoperative evaluations and visits including postoperative endoscopy.

Intervention groups

Intervention: Routine sleeve gastrectomy with concomitant cruroplasty Control/Placebo: Just routine sleeve gastrectomy without cruroplasty

Main outcome variables

Incidence of de-novo gastric reflux after sleeve gastrectomy by asking clinical symptoms of GERD (e.g. heartburn and regurgitation), esophagitis and hiatal hernia in endoscopy, and filling the GERD-QL questionnaire.

General information

Reason for update

Recruiting was expected to start after confirmation of trial and receiving the registration code. Because the approval was issued sooner, we started recruiting sooner than what has been estimated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201020049087N1**

Registration date: **2020-11-13, 1399/08/23**

Registration timing: **prospective**

Last update: **2020-12-14, 1399/09/24**

Update count: **1**

Registration date

2020-11-13, 1399/08/23

Registrant information

Name

shahab shahabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3667 1832

Email address

shshahabi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-17, 1399/08/27

Expected recruitment end date

2021-01-14, 1399/10/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effectiveness of Concomitant Cruroplasty with Sleeve Gastrectomy for Preventing De-novo Gastric Reflux after Sleeve in Patients with Severe Obesity in Comparison to Control Group Who Will Recieve The Only Sleeve Gastrectomy

Public title
Sleeve and Cruroplasty for Preventing De-novo Gastric Reflux

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Have indications for bariatric procedure according to ASMBS guideline (i.e. body mass index>40 kg/m2)
Normal gastroesophageal junction view on endoscopy No hiatal hernia on endoscopy H.pylori stool antigen negative No history of gastroesophageal reflux disease symptoms No history of consuming PPIs or antibiotics
Willingness to participate in this study Age within 20-60 years old
Exclusion criteria:
Not willing to participate in this study Pregnancy during the follow-up Severe or uncontrolled psychological disease Not respecting to the dietician and supplement use protocols Not participating in postoperative follow-up visits Not willing to do postoperative endoscopy >20% lack in medical document data Finding hiatal hernia during the operation

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

Gender
Both

Phase
N/A

Groups that have been masked
• Participant

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selecting process, and pre- and post-operative assessments. The block size will be equal and is set to 2, the sufficient and estimated sample size will be 170, then the allocation code is set to sequential. The analytics will use the output of software to determine the sequence and allocation of patients. Then each code is written on a non-transparent envelope and a paper is put

in it in which the intervention or control is written on the paper. The series of the envelope will be according to the software's list and they will keep in a large box with a locker. The analytics has the key for the box and this box will be kept in his room which the analytics has its only key and has no windows. As the patients enrolled in the study sequentially, the analytics use the designated envelope and give it to the surgeon at the time of surgery.

Blinding (investigator's opinion)

Single blinded

Blinding description

Cruroplasty will be performed at the end of sleeve gastrectomy while patient is under anesthesia. After the randomization process and defining the group of patients, the analytics say the group only to the surgeon and the surgeon who is involved in selecting patients and assessing outcomes will know about the group. Although the patient will be informed about the probability of receiving cruroplasty or not, is blinded during the surgery because of anesthesia.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

isfahan university of medical sciences deputy of ethics in medical research

Street address

Heza jarib blv. azadi sq.

City

isfahan

Province

Isfahan

Postal code

81746

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.MUI.MED.REC.1399.037

Health conditions studied

1

Description of health condition studied

severe obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

2

Description of health condition studied

Bariatric surgery status

ICD-10 code

Z98.84

ICD-10 code description

Bariatric surgery status

3

Description of health condition studied

Gastro-esophageal reflux disease without esophagitis

ICD-10 code

K21.9

ICD-10 code description

Gastro-esophageal reflux disease without esophagitis

4

Description of health condition studied

Gastro-esophageal reflux disease with esophagitis

ICD-10 code

K21.0

ICD-10 code description

Gastro-esophageal reflux disease with esophagitis

Primary outcomes

1

Description

Incidence of GERD clinical manifestations

Timepoint

before-after the surgery

Method of measurement

Taking history of reflux symptoms e.g. heartburn, regurgitation

Secondary outcomes

1

Description

GERD-Quality of Life questionnaire score

Timepoint

change in score before-after the surgery

Method of measurement

GERD-QL questionnaire

2

Description

Evidence of reflux in gastroesophageal endoscopy

Timepoint

before-after the surgery

Method of measurement

gastroesophageal endoscopy

3

Description

Evidence of hiatal hernia in endoscopy

Timepoint

before-after surgery

Method of measurement

upper endoscopy

Intervention groups

1

Description

Intervention group: Concomitant cruroplasty with routine sleeve gastrectomy. The sleeve is performed after releasing the stomach from the surrounding soft-tissue and omentum. Next, parallel to greater curvature, and with a 36 french Bougie in place, the gastrectomy will be performed using staplers. For cruroplasty, the cruses of the diaphragm bring closer with nonabsorbable sutures.

Category

Prevention

2

Description

Control group/placebo: Just routine sleeve gastrectomy without cruroplasty. The sleeve is performed after releasing the stomach from the surrounding soft-tissue and omentum. Next, parallel to greater curvature, and with a 36 french Bougie in place, the gastrectomy will be performed using staplers. The cruses of diaphragm will be observed laparoscopically for concealed hiatal hernia, but no cruroplasty with non-absorbable suture will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Minimally Invasive Surgery and Obesity Research Center

Full name of responsible person

Masoud Sayadi

Street address

Alzahra University Hospital, Sofe Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo from Isfahan University of
Medical Sciences Deputy of Research

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research@mui.ac.ir

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shahab Shahabi

Position

Advanced Laparoscopic Surgery Fellowship, General
Surgeon

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Full name of responsible person

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available