Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

Evaluating and comparison of the incidence of de-novo GERD and de-novo hiatal hernia after concomitant cruroplasty and sleeve gasterectomy with the sleeve gastrectomy alone. Evaluating and comparison of the mean of GERD-QL Questionaire score after concomitant cruroplasty and sleeve gasterectomy 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 gasterectomy 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 hiatala hernia in endoscopy who are willing to participate in this study and will complete all the postoperative evlautions and visitis 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 gasterectomy by asking clinical symptoms of GERD (e.g. heartburn and regurgitation), esophagitis and hiatal hernia in endoscopy, and filling the GERD-QL questionaire.

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 Gasterectomy for Preventing De-novo Gastric Reflux after Sleeve in Patients with Severe Obesity in Comparison to Control Group Who Will Recieve The Only Sleeve Gasterectomy

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 gasterectomy 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

Isfehan

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 gasterectomy 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 gasterectomy 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 Invsasive 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 Isfaha University of Medical Sciences Deputy of Research

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Phone
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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

Street address
Isfahan Minimally Invasive Surgery and Obesity Researhc Center, Alzahra University Hospital, Sofe Blvd. Isfahan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

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