Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Incidence of Internal Hernia and LUQ Pain Following Classic Gastric Bypass Surgery in Patients with Jejunojejunal Defect Closure Using Purse-String Versus Linear Suturing Techniques

Protocol summary

Study aim

To determine the incidence of internal hernia in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the purse string suture technique. To determine the incidence of internal hernia in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the linear suture technique. To determine the incidence of LUQ pain in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the purse string suture technique To determine the incidence of LUQ pain in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the linear suture technique. To determine the operative time in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the purse string suture technique. To determine the operative time in patients undergoing classic gastric bypass surgery with closure of the jejunojejunal defect using the linear suture technique.

Design

Sample size: 102 single-blind randomized clinical trial with SPSS Multi center

Settings and conduct

Department of Surgery at Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Patients who underwent Roux-en-Y Gastric Bypass surgery in hospitals affiliated with Isfahan University of Medical Sciences between 2024 and 2025 and were diagnosed with internal hernia and followed up for at least one year will be included.

Intervention groups

Group A: the jejunojejunal defect was closed using a purse string suture technique. Group B: the jejunojejunal defect was closed using a linear suture technique.

Main outcome variables

incidence of internal hernia, pain, patients' satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260425069164N1**
Registration date: **2026-05-13, 1405/02/23**
Registration timing: **prospective**

Last update: **2026-05-13, 1405/02/23**
Update count: **0**

Registration date

2026-05-13, 1405/02/23

Registrant information

Name

Negin Alihosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3650 2289

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iamnegin.hosseini@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-05, 1405/03/15

Expected recruitment end date

2027-06-05, 1406/03/15

Actual recruitment start date

2026-06-05, 1405/03/15

Actual recruitment end date

2027-06-05, 1406/03/15

Trial completion date
2027-07-06, 1406/04/15

Scientific title
Comparison of the Incidence of Internal Hernia and LUQ Pain Following Classic Gastric Bypass Surgery in Patients with Jejunojejunal Defect Closure Using Purse-String Versus Linear Suturing Techniques

Public title
Comparison of the Incidence of Internal Hernia and LUQ Pain Following Classic Gastric Bypass Surgery in Patients with Jejunojejunal Defect Closure Using Purse-String Versus Linear Suturing Techniques

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who underwent Roux-en-Y Gastric Bypass surgery in hospitals affiliated with Isfahan University of Medical Sciences between 2024 and 2025. Patients who were diagnosed with internal hernia and followed up for at least one year.

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **102**
Actual sample size reached: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using a block randomization table generated by SPSS version 26 (block size 4) to maintain balance between the two groups over time.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be blinded in this study. Before the surgery the surgeon will choose a card between A and B blindly and the method of intervention will be chosen.Group A will consist of patients undergoing purse-string suturing, and Group B will consist of patients undergoing linear running suturing.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Department of Medical Ethics, Ground Floor, School of Medicine, Building No. 3, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran.

City
Esfahan

Province
Isfehan

Postal code
8174673461

Approval date
2026-02-06, 1404/11/17

Ethics committee reference number
IR.MUI.MED.REC.1404.448

Health conditions studied

1

Description of health condition studied
Gastric Bypass Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Incidence of internal hernia

Timepoint
In one year after the surgery

Method of measurement
Clinical judgment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in whom the jejunojejunal defect was closed using a purse-string suture technique.

Category
Treatment - Surgery

2

Description
Intervention group: Patients in whom the jejunojejunal defect was closed using a linear suture technique.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Hamid Melali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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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
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Position
Fellowship
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only data of the primary outcomes will be shared.
When the data will become available and for how long
After publication
To whom data/document is available
Researchers, academic institutions, journals
Under which criteria data/document could be used
All requests should be sent to the corresponding author.
From where data/document is obtainable
Email the corresponding author
What processes are involved for a request to access data/document
After contacting the corresponding author, he will process and verify the request and in case of approval, the data will be emailed to you.
Comments