

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 Jejunojunal Defect Closure Using Purse-String Versus Linear Suturing Techniques

Protocol summary

incidence of internal hernia, pain, patients' satisfaction

Study aim

To determine the incidence of internal hernia in patients undergoing classic gastric bypass surgery with closure of the jejunojunal 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 jejunojunal defect using the linear suture technique. To determine the incidence of LUQ pain in patients undergoing classic gastric bypass surgery with closure of the jejunojunal 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 jejunojunal defect using the linear suture technique. To determine the operative time in patients undergoing classic gastric bypass surgery with closure of the jejunojunal defect using the purse string suture technique. To determine the operative time in patients undergoing classic gastric bypass surgery with closure of the jejunojunal 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 jejunojunal defect was closed using a purse string suture technique. Group B: the jejunojunal defect was closed using a linear suture technique.

Main outcome variables

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)

Phone

+98 31 3650 2289

Email address

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 Jejunojunal 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 Jejunojunal 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

Isfahan

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 jejunojunal defect was closed using a purse-string suture technique.

Category

Treatment - Surgery

2**Description**

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

Category
Treatment - Surgery

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina hospital
Full name of responsible person
Hamid Melali
Street address
No 173, Shamsabadi St, Isfahan City
City
Isfahan
Province
Isfahan
Postal code
813561347
Phone
+98 31 3312 5000
Email
info@sinahospital.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Melali
Street address
Medical School of Isfahan University of Medical Sciences, Hezarjerib St., Isfahan City
City
Isfahan
Province
Isfahan
Postal code
8174673461
Email
hamidmelali@yahoo.com
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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Melali
Position
Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Medical School, Isfahan University of Medical Sciences, Hezarjerib St., Isfahan City
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
009133197463
Email
hamidmelali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Melali
Position
Fellowship
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Medical School, Isfahan University of Medical Sciences, Hezarjerib St., Isfahan City
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
009133197463
Email
hamidmelali@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person

Hamid Melali

Position

Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Medical School, Isfahan University of Medical Sciences, Hezarjerib St., Isfahan City

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

009133197463

Email

hamidmelali@yahoo.com

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