# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)

**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 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
**Street address**
No 173, Shamsabadi St, Isfahan City
**City**
Isfahan
**Province**
Isfehan
**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**
Isfehan
**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**
Academic

## 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**
Isfehan
**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**
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**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**
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**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**