

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Staple Line Reinforcement on Leakage and Bleeding Rates Following Laparoscopic Sleeve Gastrectomy: A Multi-Center Study

Protocol summary

Anastomotic leakage; Bleeding

Study aim

The objective of this study was to investigate the bleeding and leakage rates following laparoscopic sleeve gastrectomy in patients with morbid obesity (Class II and Class III) after improving the surgical technique.

Design

An interventional clinical trial without a control group, non-blinded, on 107 patients to investigate the effect of staple line reinforcement on leakage and bleeding rates following laparoscopic sleeve gastrectomy

Settings and conduct

In this interventional study, 107 morbidly obese patients aged > 18 years old who underwent LSG at two hospitals in Tehran (an academic hospital and a private hospital) were evaluated. All morbidly obese patients underwent surgery by an expert bariatric surgeon. To ensure consistency and accuracy, the laparoscopic technique and the surgeon were the same for all patients. Polyglyconate and polydioxanone thread, both in full thickness, were used to reinforce the staple line.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI ≥ 40 kg/m², or ≥ 35 kg/m² with at least one comorbidity such as obstructive sleep apnea, diabetes, hypertension, obesity hypoventilation syndrome, hyperlipidemia, Pickwickian syndrome, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis (NASH), pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis, severe urinary incontinence, impaired quality of life, disqualified from another surgery due to obesity like surgery for osteoarthritis or ventral hernia repair or stress urinary incontinence (SUI) Exclusion Criteria: Age less than 18 years old, BMI < 35 kg/ m², diseases of the digestive tract, history of bariatric surgery, fundoplica

Intervention groups

Reinforcing the staple line with polyglyconate and polydioxanone sutures during a laparoscopic sleeve gastrectomy

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250109064325N1**

Registration date: **2025-02-15, 1403/11/27**

Registration timing: **retrospective**

Last update: **2025-02-15, 1403/11/27**

Update count: **0**

Registration date

2025-02-15, 1403/11/27

Registrant information

Name

Sina Eskandari Delfan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2618

Email address

eskandari.si@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-11-01, 1401/08/10

Actual recruitment start date

2021-12-31, 1400/10/10

Actual recruitment end date

2022-11-01, 1401/08/10

Trial completion date

empty

Scientific title

The Effect of Staple Line Reinforcement on Leakage and Bleeding Rates Following Laparoscopic Sleeve Gastrectomy: A Multi-Center Study

Public title

The Effect of Staple Line Reinforcement on Leakage and Bleeding Rates Following Laparoscopic Sleeve Gastrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

BMI \geq 40 kg/m², or \geq 35 kg/m² with at least one comorbidity such as obstructive sleep apnea, diabetes, hypertension, obesity hypoventilation syndrome, hyperlipidemia, Pickwickian syndrome, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis (NASH), pseudotumor cerebri, gastroesophageal reflux disease, asthma, venous stasis, severe urinary incontinence, impaired quality of life, disqualified from another surgery due to obesity like surgery for osteoarthritis or ventral hernia repair or stress urinary incontinence (SUI)

Exclusion criteria:

age less than 18 years old, BMI < 35 kg/m², diseases of the digestive tract, history of bariatric surgery, fundoplication, coagulation disorders, severe anemia (hemoglobin < 5 g/dL), and use of corticosteroids

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 107

Actual sample size reached: 107

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences ethics committee

Street address

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.358

Health conditions studied

1

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

Description

Anastomotic leakage

Timepoint

During the first 7 days and between the 1st and 6th week

Method of measurement

Radiographic evidence, reoperation to repair the anastomotic leak, percutaneous drain placement, endoscopic stent placement, abdominal abscess formation or antibiotic use for intra-abdominal abscess

Secondary outcomes

1

Description

Bleeding

Timepoint

During the first 7 days and between the 1st and 6th week

Method of measurement

re-surgery for bleeding control, blood transfusion, unexplained hemoglobin drops to less than 10 g/dL, or unexplained hematocrit drops of more than 30% if there is no specific reason for it

Intervention groups

1

Description

Intervention group: Reinforcing the staple line with polyglyconate and polydioxanone sutures during a laparoscopic sleeve gastrectomy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences, Imam Khomeini Hospital

Full name of responsible person

Ali Gandominejad

Street address

Imam Khomeini Hospital, Keshavarz blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2618

Fax

Email

ali.gandominejad71@gmail.com

2

Recruitment center

Name of recruitment center

Laleh specialized and super-specialized hospital

Full name of responsible person

Ali Gandominejad

Street address

Corner of South Shajarian St. (South Flamek), Simai Iran St., Phase 5, Shahrak Gharb, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 8856 3020

Email

ali.gandominejad71@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice Chancellor For Research, Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences Building, Gods St., Keshavarz Ave, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

141765383761

Phone

+98 21 8163 3698

Fax

Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Gandominejad

Position

General Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital surgery ward, Keshavarz blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2618

Fax

Email

ali.gandominejad71@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Gandominejad

Position

General Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital surgery ward, Keshavarz blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2618

Email

ali.gandominejad71@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Gandominejad

Position

General Surgeon

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam Khomeini hospital surgery ward, Keshavarz blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2618

Email

ali.gandominejad71@gmail.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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data will be shared after blinding of datasheet.

When the data will become available and for how long

The data access period is 6 months after the results are published.

To whom data/document is available

Data will be accessible for researchers affiliated to universities.

Under which criteria data/document could be used

Data can be used for further meta-analysis after permission of the person responsible for this project.

From where data/document is obtainable

Data request should be sent through email for the person responsible for this project. Dr. Ali Gandominejad
ali.gandominejad71@gmail.com

What processes are involved for a request to access data/document

Following the primary request, all the researchers will be informed by the responsible person and after permission the data will be shared.

Comments