Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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

Anastomotic leakage; Bleeding

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 ≥ 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, 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

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Tehran University of Medical Sciences

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Email
ali.gandominejad71@gmail.com

Person responsible for updating data

Contact

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Tehran University of Medical Sciences

Full name of responsible person
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Province
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+98 21 6119 2618

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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
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