Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of Short-term and Long-term Outcomes of Sleeve Gastrectomy With and Without Omentoplasty

Protocol summary

Study aim

Comparison of Short-term and Long-term Outcomes of Sleeve Gastrectomy With and Without Omentoplasty

Design

This study is a randomized, double-blind, parallel-group clinical trial with two arms (sleeve gastrectomy with omentoplasty vs without omentoplasty), conducted as a phase 2–3 trial in 98 patients. Randomization will be performed using permuted block randomization with a block size of four.

Settings and conduct

Both groups undergo standard 5-trocar laparoscopic sleeve gastrectomy (starting 4 cm from the pylorus over a 38-Fr bougie). In the omentoplasty group, a T-shaped omentoplasty is additionally performed by anchoring the staple line to the omentum using continuous 2/0 Ticron™ sutures up to near the angle of His.

Participants/Inclusion and exclusion criteria

Eligible participants were patients with obesity undergoing laparoscopic sleeve gastrectomy at Sina Hospital who provided written informed consent. Exclusion criteria included secondary obesity due to endocrine disorders, prior bariatric surgery, severe systemic disease or active malignancy, pregnancy or lactation, withdrawal of consent, or incomplete postoperative follow-up.

Intervention groups

In this study, which will be conducted at Imam Reza Hospital, Tabriz, patients who are candidates for sleeve gastrectomy will be divided into two groups: Group A, in which patients will undergo omentoplasty in addition to sleeve gastrectomy, and Group B, in which patients will undergo sleeve gastrectomy alone. This procedure will be performed by the specialist surgeon based on their clinical judgment.

Main outcome variables

The severity and incidence of postoperative nausea and vomiting (PONV), vitamin D, iron, zinc, fasting blood glucose, and all micronutrients (some micronutrients may be present in the original manuscript file but are currently not available here).

General information

Reason for update

The relevant variables have been added.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N77**
Registration date: **2026-06-04, 1405/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-13, 1405/04/22**
Update count: **1**

Registration date

2026-06-04, 1405/03/14

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-20, 1403/12/30

Expected recruitment end date

2026-06-21, 1405/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Short-term and Long-term Outcomes of Sleeve Gastrectomy With and Without Omentoplasty

Public title

Comparison of Short-term and Long-term Outcomes of Sleeve Gastrectomy With and Without Omentoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for sleeve gastrectomy

Exclusion criteria:

Patients with secondary obesity due to endocrine disorders Patients with a history of previous bariatric surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study with a sample size of 98 participants, patients will be allocated into two groups using the block permutation randomization method. Each block will contain 4 participants, and all possible allocation sequences will be considered, including Block 1: BBAA, Block 2: AABB, Block 3: ABAB, Block 4: BABA, Block 5: ABBA, and Block 6: BAAB. For 98 participants, 25 blocks will be used, which will be randomly selected from numbers 1 to 6 using Random Allocation Software. For example, if block number 6 is selected as the first block and block number 2 as the second block, the resulting allocation sequence will be BAABAABB, and participants will be assigned accordingly to the intervention group (A) and the control group (B). To ensure allocation concealment, the randomization list will be prepared and numbered by an independent researcher who will not be involved in patient recruitment or assessment. The assignments will then be placed in sequentially numbered, opaque, sealed envelopes. After each patient is enrolled and assigned a study code, the investigator will open the corresponding envelope in numerical order to reveal the allocated group, thereby preventing prediction of upcoming assignments.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, to ensure the proper implementation of blinding, the interventions placed in envelopes A and B will be prepared to be completely identical in terms of shape, color, packaging, and mode of administration, so that participants will be unable to distinguish between them. Each medication will be labeled with a specific code (A or B) known only to an independent researcher, who will have no direct involvement in patient recruitment or outcome assessment. The envelopes containing the medications will be provided to the study investigator in sequential order and without any indication of the treatment identity. Accordingly, both the participants and the study investigator will remain unaware of the assigned intervention, thereby maintaining double-blind conditions throughout the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, Faculty of Medicine, Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2026-01-12, 1404/10/22

Ethics committee reference number

IR.TBZMED.FMD.REC.1404.366

Health conditions studied

1

Description of health condition studied

Vitamin B12

ICD-10 code

D51.0

ICD-10 code description

Vitamin B12 deficiency anemia due to intrinsic factor deficiency

2

Description of health condition studied

Body mass index

ICD-10 code
Z68
ICD-10 code description
Body mass index [BMI]

3

Description of health condition studied
Nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

4

Description of health condition studied
Iron
ICD-10 code
E83.19
ICD-10 code description
Other disorders of iron metabolism

5

Description of health condition studied
Micronutrient
ICD-10 code
E61.8
ICD-10 code description
Deficiency of other specified nutrient elements

6

Description of health condition studied
Body mass index
ICD-10 code
Z68
ICD-10 code description
Body mass index [BMI]

Primary outcomes

1

Description
Vitamin B12
Timepoint
At 1, 3, and 6 months after surgery
Method of measurement
Blood test

2

Description
Postoperative nausea and vomiting
Timepoint
During the first week after surgery
Method of measurement
Visual Analog Scale

3

Description
Micronutrients
Timepoint
During regular postoperative follow-up visits
Method of measurement
Blood sample tests

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the omentoplasty group, the same sleeve procedure will be performed, with an additional T-shaped omentoplasty: after excision of the gastroesophageal fat pad, the staple line will be anchored to the omentum using continuous 2/0 Ticron™ sutures up to near the angle of His.
Category
Treatment - Surgery

2

Description
Control group: In the control group, standard laparoscopic sleeve gastrectomy will be performed using a five-trocar technique, with dissection starting 4 cm from the pylorus using LigaSure, sleeve creation over a 38-Fr bougie with a 60-mm stapler, and staple-line inspection with clipping if needed.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Abdolreza Mehdinavaz Aghdam
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available