

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

khanbabayimehdi69@gmail.com

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 Mehdiavaz Aghdam

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 21 3335 5921

Email

mkhanbabayi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Ajouyban@hotmail.com

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

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

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