Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Efficacy of Sleeve Gastrectomy and Gastric Bypass in Weight Loss and Control of Comorbidities (Diabetes and Hypertension) in Obese Patients

Protocol summary

Study aim

Sleeve vs. Bypass in Weight Loss and Diabetes/Hypertension Control in Obese Patients 18–65

Design

Randomized, parallel, single blind trial with blinded outcome assessor; obese surgical candidates allocated to sleeve gastrectomy or gastric bypass. Block randomization with fixed block size four and one to one ratio; outcome assessor blinded. Follow up at one, three, six, and twelve months after surgery; comparing weight loss, diabetes and blood pressure control, complications, and quality of life.

Settings and conduct

Ali Ibn Abi Talib Hospital, Zahedan, Zahedan University of Medical Sciences. After approval and ethics code, eligible patients allocated to sleeve gastrectomy or gastric bypass. Surgery in operating room; follow-up in bariatric clinic of same hospital at months 1, 3, 6, 12.

Participants/Inclusion and exclusion criteria

Inclusion: Obese adults 18 to 65, bariatric candidates, BMI 40 or more, or BMI 35 or more with diabetes or hypertension, failed nonsurgical weight loss, psychological clearance, follow-up acceptance.
Exclusion: Age outside 18 to 65, BMI below cutoff, pregnancy or lactation, type 1 or poorly controlled diabetes, severe cardiac, pulmonary, hepatic, or renal disease or malignant hypertension, psychiatric or substance abuse, eating disorder, IBD or malabsorption, prior bariatric or GI surgery, malignancy or active infection, coagulopathy or anesthesia contraindication, inability to follow up or consent.

Intervention groups

Intervention: sleeve gastrectomy versus Roux en Y gastric bypass; the latter as active comparator; identical care, follow up, and outcome assessment.

Main outcome variables

Body mass index, percent change in excess weight, glycated hemoglobin, systolic blood pressure, diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260912071016N1**
Registration date: **2026-09-20, 1405/06/29**
Registration timing: **prospective**

Last update: **2026-09-20, 1405/06/29**
Update count: **0**

Registration date

2026-09-20, 1405/06/29

Registrant information

Name

Hamid Hakiminia

Name of organization / entity

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-12-22, 1405/10/01

Expected recruitment end date

2027-12-22, 1406/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Sleeve Gastrectomy and Gastric Bypass in Weight Loss and Control of Comorbidities (Diabetes and Hypertension) in Obese Patients

Public title

Comparing the Effectiveness of Sleeve Gastrectomy and Gastric Bypass in Weight Loss and Control of Diabetes and High Blood Pressure in People with Obesity

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 18 to 65 years Body mass index equal to or greater than 40 kilograms per square meter; or Body mass index equal to or greater than 35 kilograms per square meter accompanied by at least one obesity-related comorbidity. Comorbidities (at least one of the following): Type 2 diabetes (especially poorly controlled despite medical therapy) Hypertension (especially resistant to medical therapy) History of unsuccessful weight loss: failure to achieve sustained weight loss with non-surgical methods (diet, exercise, medication) under medical supervision Psychological clearance: mental health assessment and approval by a qualified specialist Willingness for long-term follow-up: commitment to regular and lifelong follow-up after surgery

Exclusion criteria:

History of prior major abdominal surgery (other than bariatric surgery) that may have altered anatomy and makes either procedure unpredictable. Uncontrolled psychiatric disorder or inability to understand and adhere to postoperative instructions, impairing the ability to follow dietary regimens and long-term follow-up. Active substance or alcohol abuse that significantly increases the risk of postoperative complications and non-adherence to the diet. Severe and uncontrolled comorbidities (e.g., heart failure, liver failure, or advanced renal failure) that make surgical risk unacceptable.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomization will be performed using block randomization with a fixed block size of 4 and an allocation ratio of 1:1, at the individual level, without stratification. The random sequence will be generated using R/SPSS software or a random number table and then placed in opaque, sealed, and numbered envelopes. Participants will be entered into the pre-generated random sequence as follows: eligible patients, after confirmation of inclusion and exclusion criteria, provision of informed consent, and collection of baseline data, will be enrolled consecutively in the order of presentation. For each patient, an independent person will open the next numbered envelope, and the allocated group—sleeve gastrectomy or gastric bypass—will be determined according to the contents of that envelope. In this way, the pre-generated random sequence will be followed sequentially, without influence from the patient or the clinical investigator. If central randomization is used, the independent person will contact the randomization center, and the allocation for the next patient will be announced in a concealed manner. Allocation concealment will be performed using sealed envelopes or central randomization by an independent person. It should be noted that allocation concealment and blinding are two distinct processes. Allocation concealment occurs before the patient's group is revealed, in order to reduce bias in enrollment; blinding, however, is applied after allocation during the intervention or outcome assessment. In this study, blinding of patients and surgeons is not feasible, but the outcome assessor and data analyst will be blinded.

Blinding (investigator's opinion)

Single blinded

Blinding description

Accordingly, blinding will be as follows: patients and surgeons will not be blinded because the type of surgery is evident to the patient and the surgical team. The outcome assessor will be blinded to the allocated group and will not know whether patients were assigned to sleeve gastrectomy or gastric bypass at the time of outcome assessment. The data analyst will also be blinded, and group codes will remain unknown until analysis is complete. Allocation concealment before surgery will be performed using opaque, sealed, and numbered envelopes or central randomization by an independent person, so that the next patient's allocation remains concealed until enrollment. This design is described as an open-label trial with a blinded outcome assessor and a blinded data analyst.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences Ethics Committee

Street address
Medical Sciences Campus, Dr. Hesabi Square, Zahedan, Sistan and Baluchistan Province, Iran.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816743463

Approval date
2026-05-10, 1405/02/20

Ethics committee reference number
IR.ZAUMS.REC.1405.045

Health conditions studied

1

Description of health condition studied
Obesity, Type 2 Diabetes Mellitus (T2DM), and Hypertension (High Blood Pressure)

ICD-10 code
E66.813

ICD-10 code description
Obesity Class 3

Primary outcomes

1

Description
Body mass index

Timepoint
Time points for body mass index measurement: baseline (before surgery) and 1, 3, 6, and 12 months after surgery.

Method of measurement
dividing body weight in kilograms by the square of height in meters

Secondary outcomes

1

Description
glycated hemoglobin

Timepoint
baseline (before surgery) and 1, 3, 6, and 12 months after surgery.

Method of measurement
Method of measuring glycated hemoglobin: measurement using a high-performance liquid chromatography analyzer and a standard glycated hemoglobin kit.

2

Description
Hypertension control

Timepoint
baseline (before surgery) and 1, 3, 6, and 12 months after surgery.

Method of measurement
using a calibrated mercury sphygmomanometer with a stethoscope

Intervention groups

1

Description
Intervention group: Laparoscopic sleeve gastrectomy; longitudinal removal of 75–80% of the stomach with linear stapler and 36–40 Fr bougie; Veress entry, 4–5 trocars, ultrasonic energy; operative time 60–90 min, hospital stay 1–2 days. Diet/supplement education and follow-up at 1, 3, 6, and 12 months.

Category
Treatment - Surgery

2

Description
Control group: Laparoscopic Roux-en-Y gastric bypass; 25–30 mL gastric pouch with linear stapler and 18-mm bougie; small bowel divided at the ligament of Treitz; gastrojejunostomy and jejunojejunostomy; operative time 90–120 min, hospital stay 2–3 days. Same follow-up as intervention group.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abi Talib Hospital, Zahedan

Full name of responsible person
Hamid Hakimi Nia

Street address
Persian Gulf Boulevard, Surgery Department,Ali Ibn Abi Talib Hospital

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Sponsors / Funding sources

1

Sponsor

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
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Hamid Hakimi Nia

Position
Specialized Surgical Assistant

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Position
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
de-identified individual participant data (age, sex, baseline BMI, surgery type, weight, HbA1c, blood pressure, complications) for the primary outcome and diabetes/hypertension control; the full de-identified dataset is potentially shareable, though public access is usually limited to primary outcome and key comorbidity variables.
When the data will become available and for how long
It will be one year after the implementation of the project.
To whom data/document is available
University students and researchers
Under which criteria data/document could be used
Purpose: The data/documents may be used only for academic, non-commercial research, reproducibility, meta-analyses, and evaluating sleeve gastrectomy vs. gastric bypass effects on weight loss and diabetes/hypertension control in obese patients.
From where data/document is obtainable
Please refer to Dr. Hamid Hakimi, Department of Surgery, Ali Ibn Abi Talib Hospital, Zahedan, or contact him by email at dr.hakimi@zaums.ac.ir.
What processes are involved for a request to access data/document
A data/document request begins with a formal request to the study lead/ethics committee, is reviewed by the data access committee, and upon approval, a data-sharing agreement is signed and de-identified data are delivered.
Comments