Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the results of single-anastomosis gastric bypass with 150 and 180 cm biliopancreas in patients with class 3 obesity

Protocol summary

Study aim
Comparing the results of gastric bypass anastomosis with 150 and 180 cm biliopancreas in patients with class 3 obesity

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 80 patients. Blocks of four will be used for randomization.

Settings and conduct
This study is a randomized clinical trial (blocks of four), double blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 80 patients with gastric bypass surgery referred to Imam Reza Hospital (Tabriz).Patients will be randomly divided into two groups. 150 cm biliopancreas surgery method will be used for one group and 180 cm biliopancreas surgery method will be used for the other group. Finally, metabolic indices and response to surgery will be measured.

Participants/Inclusion and exclusion criteria
The most important criteria for entering the study include: class III obesity (body mass index above 40), candidate for gastric bypass surgery, surgery performed by a single surgeon and consent to participate in the study, and the most important exclusion criteria include: previous surgery on On the stomach, there will be patients with gastrointestinal cancers, patients with metabolic problems, and patients receiving any type of multivitamin for systemic problems.

Intervention groups
In this study, patients who undergo gastric bypass surgery and an anastomosis with biliopancreas of 150 and 180 cm will be included in the study. Patients will be randomly divided into two groups. 150 cm biliopancreas surgery method will be used for one group and 180 cm biliopancreas surgery method will be used for the other group. Finally, metabolic indices and response to surgery will be measured.

Main outcome variables
Body mass index changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190325043107N39**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date
2023-12-09, 1402/09/18

Registrant information

Name
Mehdi Khanbabayi Gol

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3334 7054

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khanbabayimehdi69@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-19, 1402/10/29

Expected recruitment end date
2025-01-18, 1403/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the results of single-anastomosis gastric bypass with 150 and 180 cm biliopancreas in patients with class 3 obesity

Public title
Comparison of results of single-anastomosis gastric bypass with biliopancreas in patients with class 3 obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Class III obesity (body mass index above 40) Candidate for gastric bypass surgery Surgery performed by a single surgeon Consent to participate in the study

Exclusion criteria:
Previous surgery on the stomach Patients with gastrointestinal cancers Patients with metabolic problems Patients receiving any type of multivitamin due to systemic problems

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method in order to balance the number of allocated samples, and with 4 people in each block, the whole block We put the possible ones as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose from numbers one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they will be divided into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)
Double blinded

Blinding description
The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of equipment used, in this study they will not know what type of equipment will be used in other patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Imam Reza Hospital, Azadi Ave

City
Tabriz

Province
East Azarbaijan

Postal code
5165665631

Approval date
2023-10-15, 1402/07/23

Ethics committee reference number
IR.TBZMED.REC.1402.523

Health conditions studied

1

Description of health condition studied
Body mass index changes

ICD-10 code
Z68.35

ICD-10 code description
Body mass index (BMI) 35.0-35.9, adult

Primary outcomes

1

Description
Body mass index changes

Timepoint
Once every three months for one year after surgery

Method of measurement
Weight measuring scale and meter for measuring height

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients of this group, gastric bypass will be performed laparoscopically with an anastomosis size of 150 cm, and then the body mass index will be measured for one year after the surgery and once every three months.

Category

Treatment - Surgery

2

Description

Control group: In patients of this group, gastric bypass will be performed laparoscopically with an anastomosis size of 180 cm, and then the body mass index will be measured for one year after the surgery and once every three months.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Abdolreza Mehdinavaz Aghdam

Street address
Imam Reza pital, Azadi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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

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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