

# 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 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)

##### Phone

+98 41 3334 7054

##### Email address

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 Mehdiavaz Aghdam

**Street address**

Imam Reza pital, Azadi Ave

**City**

Tabriz

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East Azarbaijan

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5166614756

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+98 21 3335 5921

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mkhanbabayi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

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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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Tabriz University of Medical Sciences

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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