

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of Roux-en-Y Gastric Bypass techniques with and without distal gastric plication in Patients with morbid obesity referring to the hospitals affiliated to the Jundishapur University of Medical Sciences, Ahvaz during 2019-2020

#### Protocol summary

##### Study aim

Comparison of Roux-en-Y Gastric Bypass techniques with and without distal gastric plication in Patients with morbid obesity

##### Design

Clinical trial with intervention and control groups, 40 patients sample size, Trial phase 2-3. Simple randomization based on random numbers table, and double blind

##### Settings and conduct

40 participants who meet inclusion criteria among patients candidates for Roux-en-Y Gastric Bypass referring to the hospitals affiliated to the Jundishapur University of Medical Sciences, Ahvaz during 2019-2020, were divided to control or intervention groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-65 years, Obesity with a BMI of more than 35 with comorbidity disease or more than 40 kg / m<sup>2</sup>, Obesity with comorbidity diseases. Exclusion criteria: Debilitating diseases, Having diseases that limit patient-physician communication, Recorded history of mental illness, Drug and alcohol abuse, Severe heart disease, Severe coagulopathy, Not accepting nutritional orders, History of gastric surgery or antireflux surgery, High-grade dysplasia in Barrett's esophagus, Severe iron deficiency anemia, Distal lesions of the stomach or duodenum require follow-up

##### Intervention groups

Intervention group: Gastric bypass by distal plication method, Like the standard method, only in this method, the stomach separated from the proximal part is folded together with a number of 2-0 nylon thread. Control group: Gastric bypass by standard method without plication, First, it is cut transversely to a distance of 5 cm from the GEJ in the form of a gastric tube, then the stomach is cut longitudinally to the cardia with a lumen 3

cm in diameter.

##### Main outcome variables

Weight Loss; Early complications; Late complications; Lipid file; Blood sugar; The amount of ghrelin hormone; Weight gain stop time.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201201049551N1**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **prospective**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

##### Registration date

2020-12-08, 1399/09/18

##### Registrant information

##### Name

Ali Sanaee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4444 9333

##### Email address

a.sanaee59@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-09, 1399/09/19

**Expected recruitment end date**

2021-06-09, 1400/03/19

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Roux-en-Y Gastric Bypass techniques with and without distal gastric plication in Patients with morbid obesity referring to the hospitals affiliated to the Jundishapur University of Medical Sciences, Ahvaz during 2019-2020

**Public title**

Comparison of two methods with and without creasing of part of the stomach in patients with morbid obesity

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18-65 years Obesity with a BMI of more than 35 with comorbidity disease or more than 40 kg / m<sup>2</sup> Obesity with comorbidity diseases Patients with consent to participate in the study

**Exclusion criteria:**

Debilitating diseases, including cancer, tuberculosis, AIDS Having diseases that limit patient-physician communication, such as Alzheimer's Recorded history of mental illness (major depression or uncontrolled psychosis) Drug and alcohol abuse Severe heart disease with risk of anesthesia Severe coagulopathy Not accepting nutritional orders History of gastric surgery or antireflux surgery High-grade dysplasia in Barrett's esophagus Severe iron deficiency anemia Distal lesions of the stomach or duodenum require follow-up Patients with no consent to participate in the study

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

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization based on random numbers table, In this way, we put a set of numbers in a completely random order without any pattern or order, set the table numbers to read from above. For intervention group we consider even numbers and for control group we consider individual numbers. Then we place one of the numbers up and down, register the number and assign it to one of the intervention or control groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

First, the study groups are explained to the participants, then, without knowing the name of the group, they enter one of the study groups. Participants and outcome assessors are not aware of any study group names.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

**Street address**

Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences, University City

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

15794-61357

**Approval date**

2019-11-08, 1398/08/17

**Ethics committee reference number**

IR.AJUMS.REC.1398.551

**Health conditions studied****1****Description of health condition studied**

Morbid obesity

**ICD-10 code**

Z68. 41

**ICD-10 code description**

Body mass index (BMI) 40.0-44.9, adult.

**Primary outcomes****1****Description**

Weight Loss

**Timepoint**

Two weeks, 1,2,6, 12 months after surgery

**Method of measurement**

The rate of weight loss two weeks after surgery is 4%, 1 month after 8%, 3 months after 18%, 6 months after

30%, 12 months after 40% relative to baseline weight.

## Secondary outcomes

### 1

#### Description

The amount of ghrelin hormone

#### Timepoint

Six, 12 months after surgery

#### Method of measurement

Pg/mL

## Intervention groups

### 1

#### Description

Intervention group: Gastric bypass by distal plication method, in the Roux-en-Y method with distal gastric plication, the gastric puncture is about 25 ml and the biliopancreatic length is 50 cm. That like the standard method, only in this method, the stomach separated from the proximal part is folded together with a number of 2-0 nylon thread. The remaining stomach volume is 25 ml.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Gastric bypass by standard method without plication, in the Roux-en-Y method with distal gastric plication, the gastric puncture is about 25 ml and the biliopancreatic length is 50 cm. First, it is cut transversely to a distance of 5 cm from the GEJ in the form of a gastric tube, then the stomach is cut longitudinally to the cardia with a lumen 3 cm in diameter. The volume of the remaining stomach is 25 ml, which is inserted into the small intestine 80-120 cm in the distal position of the small intestine after anastomosis with the help of 2-0 Continius prolen.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The hospitals affiliated to the Jundishapur University of Medical Sciences, Ahvaz

##### Full name of responsible person

Mehdi Askari

##### Street address

Farvardin St.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

33118-61357

##### Phone

+98 61 3374 3001

##### Email

askari-m@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badvi P.H.D

##### Street address

Vice Chancellor for Research and Technology Ahvaz Jundishapur University of Medical Sciences, University City

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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

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehdi Askari M.D

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

General Surgery

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Farvardin St.  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Mehdi Askari M.D  
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Assistant Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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Assistant Professor  
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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

The whole data can be shared after unidentifiable people.

### When the data will become available and for how long

Start the access period 6 months after printing the results

### To whom data/document is available

Only available to scholars working in academic and academic institutions

### Under which criteria data/document could be used

Employed in research centers

### From where data/document is obtainable

Person responsible for scientific inquiries

### What processes are involved for a request to access data/document

Send email to person responsible for scientific inquiries

### Comments