# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

# The effect of 30 and 45 mm gasterojejunal anastomosis size with fixed 125 cm biliopancreatic limb and 75 cm alimentary limb on Excess Body Mass Index Loss (EBMIL) and Roux-en-Y bypass outcomes in the patients with morbid obesity; a double- blinded clinical trial

## Protocol summary

**Study aim**

Investigating the effect of 30 and 45 mm gasterojejunal anastomosis size with fixed 125 cm biliopancreatic limb and 75 cm alimentary limb on Excess Body Mass Index Loss (EBMIL) and Roux-en-Y bypass outcomes in the patients with morbid obesity; a double- blinded clinical trial

**Design**

A clinical trial with parallel, double-blind, randomized by permuted block randomization, performed on 70 patients in the two equal groups.

**Settings and conduct**

This study will be carried out on 70 patients who are candidates for bariatric surgery by Roux-en-Y method in Hazrat-e-Rasoul Akram and Atiyeh hospitals in Tehran. The two groups with gasterojejunal anastomosis sizes of 30 and 45 mm will be randomly assigned to the study groups. The randomization method is permuted block randomization.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Candidate for Roux-en Y surgery, satisfaction to participate in the study, age over 18 years, body mass index more or equal to 40 and less or equal to 50. Exclusion criteria: History of major gastrointestinal surgery, having general conditions that prevent surgery under general anesthesia, age over 75 years, having Crohn's inflammatory disease, family history of gastric cancer , severe intestinal adhesions

**Intervention groups**

Intervention group 1 (second surgical technique): Recipient of gasterojejunal anastomosis with a size of 45mm: Intervention group 2 (second surgical technique): Recipient of gasterojejunal anastomosis with a size of 30 mm

**Main outcome variables**

Excess Body Mass Index Loss (EBMIL), diabetes remission, HOMA-IR, FBS, 2HPP, C-Peptide, HbA1C, lipid profile, liver profile, systolic and diastolic blood pressure, dumping, hemoglobin and albumin

## General information

**Reason for update**

Modification in sample size

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180507039572N1**
Registration date: **2021-02-13, 1399/11/25**
Registration timing: **prospective**

Last update: **2022-06-28, 1401/04/07**
Update count: **2**

**Registration date**

2021-02-13, 1399/11/25

**Registrant information**

**Name**

Rohollah Valizadeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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rohvali4@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-03-05, 1399/12/15

**Expected recruitment end date**

2021-08-21, 1400/05/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of 30 and 45 mm gasterojejunal anastomosis size with fixed 125 cm biliopancreatic limb and 75 cm alimentary limb on Excess Body Mass Index Loss (EBMIL) and Roux-en-Y bypass outcomes in the patients with morbid obesity; a double- blinded clinical trial

**Public title**

The effect of gasterojejunal anastomosis size on Excess Body Mass Index Loss (EBMIL) and Roux-en-Y bypass outcomes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Candidate for Roux-en Y surgery Satisfaction to participate in the study Age over 18 years Body mass index more or equal to 40 and less or equal to 50

**Exclusion criteria:**

History of major gastrointestinal surgery Having general conditions that prevent surgery under general anesthesia Age over 75 years Having Crohn's inflammatory disease Family history of gastric cancer Severe intestinal adhesions

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, we will create random numbers in a column, so the Rand () function in Excel will be used. Then we will consider the random numbers below the half as 4 blocks and the numbers above the half as 6 blocks. For this purpose, the symbols O30 and O45 have been used for 30 and 45 mm interventions. The procedure is as follows: in block 4, two O30 interventions and two O45 interventions will be written in a column first. More column will then be assigned 4 random numbers using the Rand () function. The order of the assigned random numbers will then be sorted from small to large to change the order of our intervention codes. The same thing will be repeated for a block of 6. This process continues until we reach an equal number of control and intervention groups. After generating random numbers without repetition, a number is assigned to each assigned sequence along with the type of intervention, and will be placed in a sealed envelope whose contents are not known, so that the operating room nurse will pick up one of the 70 envelopes for qualified patient and will inform the type of group to surgeon after tearing the sealed envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and outcome assessors will be unaware of the allocated study groups. Due to the fact that the intervention is necessarily performed by the surgeon, so there is no possibility of blinding the surgeon and the surgeon is aware of the group type.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences., next to Milad tower., Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2021-02-09, 1399/11/21

**Ethics committee reference number**

IR.IUMS.REC.1399.1227

## Health conditions studied

### 1

**Description of health condition studied**

Diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

### 2

**Description of health condition studied**

Morbid obesity

**ICD-10 code**
E66.01
**ICD-10 code description**
Morbid (severe) obesity due to excess calories

## Primary outcomes

### 1

**Description**
Excess Body Mass Index Loss (EBMIL)
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Using the following formula obtained from the body mass index: (Pre-operative BMI – Current BMI) / (Pre-operative BMI – 25) × 100

## Secondary outcomes

### 1

**Description**
Diabetes remission
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Using Buchwald criteria (FPG <100 mg/dl or A1C <6 %)

### 2

**Description**
Insulin
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 3

**Description**
Fasting blood sugar
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 4

**Description**
Glocuse, 2 hour Post Prandial
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 5

**Description**
C-Peptide
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 6

**Description**
HbA1C
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 7

**Description**
Lipid profile
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 8

**Description**
Systolic blood presser
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Barometer

### 9

**Description**
Diastolic blood pressure
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Barometer

### 10

**Description**
Dumping
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Physical examination

### 11

**Description**
Hemoglobin

**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 12

**Description**
Liver porfile
**Timepoint**
Before the intervention, one, three and six months after the intervention
**Method of measurement**
Blood sampling

### 13

**Description**
Quality of life
**Timepoint**
Six months after the intervention
**Method of measurement**
BAROS quality of life consisting of 5 items (self-esteem, work conditions, physical activity, social activity and sexual Activity). Each item consists of 5 options (much better, better, similar, worse and much worse).

## Intervention groups

### 1

**Description**
Intervention 1 "Receiving 45 mm gasterojejunal anastomosis": Patients in this group will be placed in French (Y-shaped) surgical position after general anesthesia so that the surgeon can stand between the patient's legs. Five trocas will be used to perform Roux-en Y bariatric laparoscopy. The first optical troca (with camera) is placed 10 cm from the xiphoid process in the medline line, and then the other two trocas will be placed to the right (10 mm) and left (5 mm) of the medline line. Also, two 5 mm trocas will be placed at the bottom of the umbilicus at a distance of approximately 20 cm from each other. The "Angle of His" between the stomach and esophagus is released. After implanting a gastric pouch that is 6 cm long with an approximate volume of 30 to 60 ml, 125 cm from the proximal part of the small intestine will be calculated to prepare it for anastomosis with a 45 mm gastric linear stapler and then 75 cm from the distal part to the gasterojejunostomy site, a hole will be made to make a gasterojejunal anastomosis.
**Category**
Treatment - Surgery

### 2

**Description**
Intervention 2 "Receiving 30 mm gasterojejunal anastomosis": Patients in this group will be placed in French (Y-shaped) surgical position after general anesthesia so that the surgeon can stand between the patient's legs. Five trocas will be used to perform Roux-en Y bariatric laparoscopy. The first optical troca (with camera) is placed 10 cm from the xiphoid process in the medline line, and then the other two trocas will be placed to the right (10 mm) and left (5 mm) of the medline line. Also, two 5 mm trocas will be placed at the bottom of the umbilicus at a distance of approximately 20 cm from each other. The "Angle of His" between the stomach and esophagus is released. After implanting a gastric pouch that is 6 cm long with an approximate volume of 30 to 60 ml, 125 cm from the proximal part of the small intestine will be calculated to prepare it for anastomosis with a 30 mm gastric linear stapler and then 75 cm from the distal part to the gasterojejunostomy site, a hole will be made to make a gasterojejunal anastomosis.
**Category**
Treatment - Surgery

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rasool Akram Hospital
**Full name of responsible person**
Masoud Solaymani-Dodaran
**Street address**
Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh “St.”,Sattarkahn “Ave.”, Tehran
**City**
Tehran
**Province**
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**Postal code**
1445613131
**Phone**
+98 21 6651 5001
**Email**
msdodran@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Iran University of Medical Sciences
**Full name of responsible person**
Seyyed Abas Motavalian
**Street address**
Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1433933111
**Phone**
+98 21 6650 9059
**Email**
amotevalian@yahoo.com

**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iran 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**
Iran University of Medical Sciences
**Full name of responsible person**
Rohollah Valizadeh
**Position**
PhD student
**Latest degree**
Master
**Other areas of specialty/work**
Epidemiology
**Street address**
Hazrat-e-Rasoul Hospital, Sattar Khan Ave.
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## Person responsible for scientific inquiries

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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**
All patient's data will be provided anonymously to researchers. The findings of the study will be presented publicly.
**When the data will become available and for how long**
Immediately after the publication of the article

**To whom data/document is available**

Academic researchers and faculty members

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

For research purposes only

**From where data/document is obtainable**

Email must be sent to the responsible for scientific inquiries (msdodran@gmail.com)

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

Email must be sent to the responsible for scientific inquiries (msdodran@gmail.com)

**Comments**