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 / m2, 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

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Iran (Islamic Republic of)

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+98 21 4444 9333

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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 / m2 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
Khouzestan
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.
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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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askari-m@ajums.ac.ir
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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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
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