

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparative study of the effect of two 3.5 x 30 and 45 * 3.5 mm jejunum incisions during gastric bypass gastrectomy on weight of obese patients

Protocol summary

Study aim

Comparison of the effect of two 3.5 x 45 and 3.5 x 45 mm jejunal bypasses on the weight of obese patients

Design

Fifty patients undergoing gastric bypass surgery were randomly assigned into two groups of 25 each. In the first group, the jejunum is cut at 30 x 3.5 mm in the first group and 40 x 3.5 x 2 mm in the second group. All patients were followed up at one month, three months and 6 months after surgery and weight loss rates were compared between the two groups.

Settings and conduct

In this single-blind clinical trial will be done in Alzahra Hospital of Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: BMI between 40 and 50, age of over 40 years old, consent to participate in the study. Exclusion criteria: Hypothyroidism, diabetes

Intervention groups

Intervention group 1: 3.5 x 30 mm incision in gastric jejunostomy. Intervention group 2: 45 x 3.5 mm diameter incision in gastric jejunostomy

Main outcome variables

Weight changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130311012782N45**

Registration date: **2020-03-20, 1399/01/01**

Registration timing: **prospective**

Last update: **2020-03-20, 1399/01/01**

Update count: **0**

Registration date

2020-03-20, 1399/01/01

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3629 1510

Email address

mehrabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of two 3.5 x 30 and 45 * 3.5 mm jejunum incisions during gastric bypass gastrectomy on weight of obese patients

Public title

The effect of gastric resection on the weight of obese patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age lower 40 years Range of Body Mass Index between 40-50 agree to participate in the study

Exclusion criteria:

Performing previous abdominal surgery Hypothyroidism
Diabetes

Age

From 40 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized sari is performed between the two groups using random allocation software. So that the sample size is first entered into the software and then the number of groups is determined. The software output is a list that distributes 80 samples randomly into groups. Patients are divided into two groups according to the time of referral in order to reach the required sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be done in a single blind and patients are unaware about the length of the narrow intestine that is removed during surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Soffeh Street, Alzahra hospital

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-06-11, 1398/03/21

Ethics committee reference number

IR.MUI.MED.REC.1398.333

Health conditions studied

1

Description of health condition studied

Excessive Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

Weight changes

Timepoint

1, 3 and 6 months after surgery

Method of measurement

By using Body Mass Index, calculated by square of height(m) divided to wieght (kg)

Secondary outcomes

1

Description

Changes of serum level of Albumin

Timepoint

1,3 and 6 months after operation

Method of measurement

Blood sample and laboratory test

Intervention groups

1

Description

Intervention group 1: Cut jejunum at 3.5 x 30 mm in gastric bypass. Intervention group 2: jejunal incision at 3.5 x 45 mm in gastric bypass.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital of Isfahan

Full name of responsible person

Mohamad Harandizadeh

Street address

Soffeh Street, Alzahra hospital

City

Isfahan

Province

Isfahan

Postal code

8174673461
Phone
+98 31 3669 2174
Email
dr_harandizadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 3070
Email
haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Behrouz Keleidari
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Hezar Jarib Street
City

Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3669 2174
Email
keleidari@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohsen Mahmoudieh
Position
Associated Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Soffeh Street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3669 2174
Email
mahmoudieh@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Mehrabi
Position
Statistical consultant
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Hezar Jarib Street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3792 8081
Email
al.mehrabi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data belongs to a governmental agency

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Due to the fact that the information belongs to the governmental organization, it is not possible to share it.

When the data will become available and for how long

Any time

To whom data/document is available

Every person

Under which criteria data/document could be used

any status

From where data/document is obtainable

Any person

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

Any process

Comments