

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of Laparoscopic One Anastomosis Gastric Bypass and Carbajo's gastric bypass on incidence of bile reflux in morbid obese patients: a randomized controlled clinical trial

Protocol summary

Study aim

- Investigation of the effect of bariatric surgery on the presence of biliary reflux in patients with obesity

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 100 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

People with obesity who go to the obesity clinic of Rasoul Akram Hospital will be examined after being examined by the obesity clinic team and BMI calculation and if they have the conditions. They are then placed in control and carbajo groups. The study participants were examined using radioactive materials according to the HIDAscan procedure 12 months after surgery. If the syntax is positive, the patient will undergo endoscopy and pH. If the patient complains of reflux symptoms or the GERDQ questionnaire is positive but the chest x-ray is negative, then the patient will be treated with oral pantoprazole at a dose of 40 mg every 12 hours for 6 weeks and if not resolved. Symptoms will be directed to the patient for endoscopy and pH. Patients are divided into two groups using four randomized blocks.

Participants/Inclusion and exclusion criteria

- BMI $\geq$ 40 • BMI $\geq$ 35 > 40 with at least one complication associated with obesity with failure of conventional non-surgical treatments • BMI $\geq$ 30 with diabetes with recent onset • Acceptable surgical risk • Complete and sign the consent form for participation in the study and commit to return for further follow-up • Treatment with OAGB or Carbacho surgery

Intervention groups

- 1- Single anastomosis gastric bypass technique with carbajo technique
- 2- Traditional single anastomosis gastric bypass group

Main outcome variables

Gastroesophageal bile Reflux Disease (GERD): weight loss; esophageal mucousal change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042520N2**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-26, 1401/04/05**

Update count: **1**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Mohammad Kermansaravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8809 5451

Email address

kermansaravi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effect of Laparoscopic One Anastomosis Gastric Bypass and Carbajo's gastric bypass on incidence of bile reflux in morbid obese patients: a randomized controlled clinical trial

Public title
the effect of Carbajo's surgical technique on bile reflux

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 BMI $\geq$ 40 BMI $\geq$ 35 > 40 with at least one obesity-related complication with failure of conventional non-surgical treatments BMI $\geq$ 30 with diabetes with recent onset Acceptable surgical risk Complete and sign the informed consent of the company to participate in the study and commit to return for further follow-up OAGB or Carbajo surgery
Exclusion criteria:
 Obesity due to treatable endocrine diseases such as Cushing's • High risk of anesthesia after heart and lung counseling • Diagnosing the surgeon based on the high risk of surgery • Drug addiction • Lack of mental health: Serious psychological problem including psychosis and severe uncontrollable depression at the discretion of the specialist Pregnancy or pregnancy planning for the next two years in married women of childbearing age Severe preoperative reflux: GERD Score greater than or equal to eight according to the GERD Q questionnaire Severe to moderate severe or severe herniated epilepsy according to endoscopy

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into two groups using four randomized blocks. One of the statistical specialists who is not present in the project is responsible for randomly assigning individuals to the two groups after examining the achievement of admission criteria. (One of the two methods mentioned above), he is contacted and he tells us the type of surgery that is going to be performed.

Blinding (investigator's opinion)
Single blinded

Blinding description
The patient is not aware of his surgical procedure, but we

will explain to him about these two methods, and the purpose of this study will be explained to him. They are explained and after obtaining informed consent, they enter the study. In this study, the doctor who performs the surgery is definitely aware of the surgical procedure. To minimize the surgeon's awareness error, the doctor who evaluates the reflux is different from the surgeon, but despite this, the study is considered single blind.

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

Shahid Hemmat Highway

City

tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.IUMS.REC.1399.211

Health conditions studied

1

Description of health condition studied

morbid obesity

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

GastroEsophageal Reflux Disease

Timepoint

12 months after surgery

Method of measurement

Cintigraphy after assessment of GERD-Q

(gastroesophageal reflux disease questionnaire) equal or more than 8

Secondary outcomes

empty

Intervention groups

1

Description

1- Typical one-anastomosis bypass method: In the distal area, we enter the crow's foot to crow's foot, and on the 36 F bougie, using a few 60 mm endo staplers with a suitable staple height, the stomach pouch is made long and narrow. In the next step, gastrojejunal anastomosis is performed with 45 mm blue stapler and the intestinal site is sutured with 2-0 PDS sutures from 150 to 200 cm depending on BMI, age, height and comorbidities

Category

Treatment - Surgery

2

Description

2. Single anastomosis bypass with Carbajo technique: In Carbajo method, the steps are the same as traditional method and only a few differences are seen: 1- The length of the pouch is 13 to 15 cm. 2. Gastrojejunal anastomosis is 2 to 2.5 cm. 3. The length of the biliopancreatic limb is 250 to 350 cm on average. 4. The proximal portion of the gastrojejunal anastomosis is 8 to 10 cm long and sewn to the pouch and then to the remnant in the opposite direction of gravity.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital Obesity Clinic

Full name of responsible person

Mohammad Kermansaravi

Street address

Sattarkhan street

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6655 5447

Email

mkermansaravi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Abdolreza Pazouki

Street address

Sattarkhan

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6655 5447

Email

mkermansaravi@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

Mohammad Kermansaravi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

No 17 .Morvarid 3.Sadaf Ave.Dadman Blvd.Qods Town

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 8809 5451

Fax

Email

kermansaravi.m@iums.ac.ir

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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
etics**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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Clinical study report

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

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

No example

From where data/document is obtainable

No example

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

No example

Comments

Person responsible for updating data

Contact

Name of organization / entity

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