

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation the efficacy of anterior cruroplasty versus posterior cruroplasty in improvement of Gastroesophageal reflux disease (GERD) after One Anastomosis Gastric Bypass (OAGB)

Protocol summary

Study aim

Evaluation the efficacy of anterior cruroplasty vs posterior cruroplasty in improvement of Gastroesophageal reflux disease (GERD) after One-Anastomosis Gastric Bypass (OAGB)

Design

Clinical trial, with parallel groups, single-blind, randomized, on 90 patients

Settings and conduct

This trial will be conducted on 90 patients in Rasool-e Akram hospital. Patients will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 < BMI < 50, 18 < age < 65, Primary bariatric surgery OAGB Surgical Procedure, BP Limb of 150 cm, Anastomosis diameter 4 cm Symptomatic clinical GERD before OAGB, GERD grade A, B, C in pre-op endoscopy, Any size of hiatal hernia. Exclusion criteria were: High risk of anesthesia after heart and lung counseling, Diagnosing the surgeon based on the high risk of surgery, Lack of mental health: Serious psychological problem including psychosis and severe, uncontrollable depression at the discretion of the specialist, and Barrett's esophagus in pre-op endoscopy.

Intervention groups

1- Intervention group: One anastomosis gastric bypass without cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot with a 40mm gastr-jejunostomy about 150cm distal to Treitz' ligament. 2- Intervention group: One anastomosis gastric bypass with anterior cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot with a 40mm gastrojejunostomy about 150cm distal to Treitz' ligament. Then an anterior cruroplasty is performed with Ethibond 2-0. 3- Intervention group: One anastomosis gastric bypass with posterior cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot

with a 40mm gastrojejunostomy about 150cm distal to Treitz' ligament. Then a posterior cruroplasty is performed with Ethibond 2-0.

Main outcome variables

Status of Gastroesophageal Reflux

General information

Reason for update

Hello. Respectfully The applied changes are: sample size: 90 (in three groups of 30) - place of study: Rasool-e Akram Hospital

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042520N4**
Registration date: **2022-11-23, 1401/09/02**
Registration timing: **prospective**

Last update: **2024-01-06, 1402/10/16**

Update count: **1**

Registration date

2022-11-23, 1401/09/02

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

2023-01-20, 1401/10/30
Expected recruitment end date
2024-01-20, 1402/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the efficacy of anterior cruroplasty versus posterior cruroplasty in improvement of Gastroesophageal reflux disease (GERD)after One Anastomosis Gastric Bypass (OAGB)

Public title
Evaluation the efficacy of diaphragmatic hernia repair in improvement of Gastroesophageal reflux disease (GERD)after One Anastomosis Gastric Bypass (OAGB)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

40<BMI<50 18<age<65 Primary surgery OAGB Surgery Biliopancreatic limb length of 150 cm Anastomosis length of 4 cm Symptomatic clinical reflux before surgery Reflux grade A, B, C in endoscopy Having hiatal hernia in any size

Exclusion criteria:

High risk of anesthesia after heart and lung counseling
Diagnosing the surgeon based on the high risk of surgery
Lack of mental health: Serious psychological problem including psychosis and severe uncontrollable depression at the discretion of the specialist Barrett's esophagus in pre-op endoscopy

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use Block Randomization method with six block sizes. Excel software and rand() function will be used to prepare random order inside each block. We will have 3 groups of 30 people. When the intervention of each participant is determined, then a unique four-digit code will be assigned to the person (concealment). This number is the randomization code of the participant and the person will be identified with this number until the end of the study. A chain of 90 random allocations for use in the first phase of the study will be kept by the main investigator.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients are not aware about the type of surgery, but all types will describe before performing surgery and the aim of study completely clarify for them. This issue that the efficacy of these three methods on postoperative reflux is unknown, completely describe for the patients and they include in study after obtaining the informed consent.

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

1449614535

Approval date

2022-11-16, 1401/08/25

Ethics committee reference number

IR.IUMS.REC.1401.646

Health conditions studied

1

Description of health condition studied

Gastro-esophageal reflux disease

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Gastroesophageal Reflux Disease

Timepoint

Before surgery and 7 months after surgery

Method of measurement

Upper GI Endoscopy (esophagogastroduodenoscopy)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: One anastomosis gastric bypass without cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot with a 40mm gastr-jejunostomy about 150cm distal to Trietz' ligament.

Category

Treatment - Surgery

2

Description

Intervention group 2: One anastomosis gastric bypass with anterior cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot with a 40mm gastr-jejunostomy about 150cm distal to Trietz' ligament. Then an anterior cruroplasty is performed with Ethibond 2-0.

Category

Treatment - Surgery

3

Description

Intervention group 3: One anastomosis gastric bypass with posterior cruroplasty: The pouch is created as a narrow and long pouch over a 36Fr bougie distal to Crow's foot with a 40mm gastr-jejunostomy about 150cm distal to Trietz' ligament. Then an posterior cruroplasty is performed with Ethibond 2-0.

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

Rasool-e Akram hospital, Niyayesh street, Sattarkhan street

City

Tehran

Province

Tehran

Postal code

1449614535

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

Seyyed Kazem Malakuti

Street address

Iran University of Medical Science., Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

PR@iums.ac.ir

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, 3th Morvarid, Sadaf Ave, Dadman Blvd, Qods Town

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 8809 5451

Email

kermansaravi.m@iums.ac.ir

Person responsible for scientific 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, 3th Morvarid, Sadaf Ave, Dadman Blvd, Qods Town

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8809 5451

Email

kermansaravi.m@iums.ac.ir

Web page address**Person responsible for updating data****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, 3th Morvarid, Sadaf Ave, Dadman Blvd, Qods Town

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8809 5451

Email

kermansaravi.m@iums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available