Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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