Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of anti-reflux suture in gastric bypass single anastomosis in order to prevent biliary reflux

Protocol summary

Study aim

Determining the effect of using anti-reflux suture in gastric bypass single anastomosis in order to prevent biliary reflux.

Design

This clinical trial has 2 groups (control and intervention), double-blind, randomized, with a sample size of 60 patients, random number table is used for randomization.

Settings and conduct

The study will be conducted on 60 patients with indications for bariatric surgery admitted to Ayatollah Yasrebi Hospital in Kashan in 1403-1402. People will be randomly divided into 2 groups of 30 people, both groups in the study will benefit from a similar and standardized surgical procedure, and only at the end of the operation, antireflux suture will be performed for the intervention group, which won't be done in the control group.This study is a double blind study, the first person collects the information and the second person analyzes the information, in such a way that the researcher in charge of the project randomly divides the people into 2 groups and provides the list of 2 groups with the person who collects the information and the person who analyzes the information.

Participants/Inclusion and exclusion criteria

1. Clients aged 20 to 50 years 2. Having a BMI above 30 3. Patient satisfaction

Intervention groups

Both groups in the study will benefit from a similar and standardized surgical procedure, and only at the end of the operation, antireflux suture will be performed for the intervention group, which will not be done in the control group.

Main outcome variables

HTN; FBS; history of HHR (hiatal hernia repair); nasea and vomiting after the surgery; BMI before the surgery; BMI after the surgery; GERD score; age; sex; VAS score; antireflux suture.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231201060232N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Fateme Zare Rahimi Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3726 6742

Email address

fzarefzr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of anti-reflux suture in gastric bypass single anastomosis in order to prevent biliary reflux

Public title
Evaluation of the effect of anti-reflux suture in gastric bypass single anastomosis in order to prevent biliary reflux
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Clients aged 20 to 50 years Having a BMI above 30 Patient satisfaction
Exclusion criteria:
Non-cooperation of the patient to participate in the intervention People who consume alcohol and smoke
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is done by a simple random method and randomization is done using a table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double blind study, the first person collects the information and the second person analyzes the information, in such a way that the researcher in charge of the project randomly divides the people into 2 groups 1 and 2 and the list of two It provides the group with the person who collects the information and the person who analyzes the information.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kashan University of Medical Sciences
Street address
Kashan university of medical sciences, Ghotbe Ravandi Blv., Kashan, Isfahan
City
Kashan
Province
Isfehan
Postal code
8715981151
Approval date
2023-12-25, 1402/10/04
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.220

Health conditions studied

1

Description of health condition studied
Antireflux suture; gastric bypass single anastomosis (oagb) ; biliary reflux
ICD-10 code
Diseases o
ICD-10 code description
Diseases of the digestive system

Primary outcomes

1

Description
GERD score
Timepoint
2 weeks, one month, 3 month and 6 month after the surgery
Method of measurement
Gastroesophageal reflux disease questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In omega bypass surgery (OAGB) , after creating a stomach pouch and performing gastrojejunostomy anastomosis and leak test (by air and methylene blue), an antireflux suture is applied in such a way that the proximal part of the small intestine efferent loop is left to the lowest part of the remaining stomach with a non-absorbable thread. Finally, a drain is placed for the patient and the patient's skin is sutured and the operation is finished.
Category
Prevention

2

Description

Control group: In omega bypass surgery, after creating a stomach pouch and performing a gastrojejunostomy anastomosis and leakage test (by air and methylene blue), a drain is placed for the patient and the patient's skin is sutured and the operation ends. for the patients of this group, antireflux suture is not applied.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Yasrebi Hospital of Kashan

Full name of responsible person

Fateme Zare Rahimi Abadi

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blv., Kashan, Isfahan

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fzarefzr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hossein Sadeghi

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blv., Kashan, Isfahan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

0

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

Kashan University of Medical Sciences

Full name of responsible person

Fateme Zare Rahimi Abadi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

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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
All study data can be provided except for demographic data.
When the data will become available and for how long
After performing statistical analysis and determining the relationship between the variables, it can be presented.
To whom data/document is available
The study data is accessible to all people on the condition of receiving approval from the university's ethics committee.
Under which criteria data/document could be used
The people who receive the data must obtain permission to access the data from the ethics committee. There are no restrictions in terms of performing tests and statistical analyses.
From where data/document is obtainable
The documents and findings of the study will be published in the form of an article and will be accessible in databases, and since the study is a thesis, it will also be accessible in Kashan University of Medical Sciences.
What processes are involved for a request to access data/document
The applicant should submit a request for access to the data by submitting an official request from an official body to the ethics committee of Kashan University of Medical Sciences.
Comments