Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of using ursodeoxycholic acid and using placebo in incident of gallstone after laparoscopic gastrectomy

Protocol summary

Study aim
The aim was to compare incidence of gallstone between two groups, a group with using ursodeoxycholic and using placebo.

Design
This study is a randomized clinical trial on 100 patients with control group, with parallel groups, (ursodeoxycholic acid and placebo). This study is of double-blind nature. We used a random number table to randomize patients in both groups.

Settings and conduct
In this clinical trial study patients undergoing Laparoscopic sleeve gastrectomy in 2020 will be enrolled in this study.Patients are randomly divided into two treatment groups using ursodeoxycholic and using placebo.Patients, Evaluator and analyzers are blind . The form of pill was the same in both groups, and the Patients, Evaluator and analyzers did not know what group the patients are in. incidence of gallstone between two groups, will be compared

Participants/Inclusion and exclusion criteria
In this clinical trial study patients with Laparoscopic sleeve gastrectomy will be included in the study. Exclusion criteria included patient with past history of cholecystectomy ,gallbladder agenesia and patient who didn't sign the consent form.

Intervention groups
Treated with using ursodeoxycholic and using placebo.

Main outcome variables
incidence of gallstone

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200708048049N1**
Registration date: **2020-08-12, 1399/05/22**
Registration timing: **registered_while_recruiting**
Last update: **2020-08-12, 1399/05/22**
Update count: **0**

Registration date
2020-08-12, 1399/05/22

Registrant information

Name
Sara Besharat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2207 4087

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besharat.sara@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

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
Comparison of using ursodeoxycholic acid and using placebo in incident of gallstone after laparoscopic gastrectomy

Public title
The effect of using ursodeoxycholic acid in incident of gallstone in laparoscopic sleeve gastrectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
- patients undergoing Laparoscopic sleeve gastrectomy - morbid obesity (BMI more than 40 kg/m2 in healthy people and more than 35 kg/m2 with comorbidity)
Exclusion criteria:
- patient with past history of cholecystectomy - patient with gallbladder agenesia -patient who didn't sign the consent form.

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups with using ursodeoxycholic acid and using placebo .we used a random number table for randomization of Patients in two groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients, Evaluator and analyzers are blind to the study. The form of pill was the same in both groups, and the Patients, Evaluator and analyzers did not know what group the patients are in.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
School of Medicine, Shahid Beheshti University of Medical Sciences, Arabi Ave., Daneshjoo Blvd., Velenjak
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.272

Health conditions studied

1

Description of health condition studied
Morbid obesity
ICD-10 code
E66.8
ICD-10 code description
Other obesity

Primary outcomes

1

Description
Gallstone
Timepoint
Before sleeve gastrectomy surgery, 6 and 12 months after surgery
Method of measurement
Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Treated with using ursodeoxycholic (kushan pharmed, Tehran, Iran) daily
Category
Treatment - Drugs

2

Description
Control group:Treated with using placebo daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres hospital
Full name of responsible person
Naser Malekpur Alamdari
Street address
Saadat Abad Ave., Yadegar Emam Expressway,

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyyed Ali Ziai
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Danshju Ave Velenjak
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aliziai@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

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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
There is no more information
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
No - There is not 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