Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Determination of effect of Ursodeoxycholic acid on gallstone in pateint undergoing bariatric surgery while having asymptomatic gallstone

Protocol summary

Study aim
Determining the effect of ursodeoxycholic acid drug on gallstones in patients undergoing bariatric surgery and with asymptomatic cholecystitis before surgery.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase one on 60 patients, is prepared for randomization using the method of four random blocks. The randomization unit is individual and the randomization tool is PASS11 statistical software

Settings and conduct
This study is a randomized clinical trial including 60 patients with morbid obesity and asymptomatic gallstones, which was designed in a double-blind manner. Patients referred to the obesity research center of Hazrat Fatemeh Hospital are randomly divided into the following two groups (randomized block method): The first treatment group is the use of ursodeoxycholic acid 300 mg twice a day for six months. The second treatment group will be placebo for 6 months. Before and after the intervention, the number and size of gallstones are measured by ultrasound. All ultrasounds are performed by a single radiologist and a single ultrasound machine. will not be included in the study group.

Participants/Inclusion and exclusion criteria
Inclusion criteria include morbidly obese patients who are candidates for bariatric surgery (Sleeve, Classic Bypass or OAGB) and have asymptomatic gallstones.

Intervention groups
The group receiving the medicine will receive UDCA capsules (Ursobil) made by the AANIDARMAN company with a dose of 300 mg every 12 hours for 6 months for free. The control group also receives a placebo drug with the same appearance as the main drug for the same duration

Main outcome variables
number of gallstones; The size of gallstones; complications of gallstones

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190128042520N5**
Registration date: **2024-01-26, 1402/11/06**
Registration timing: **prospective**

Last update: **2024-01-26, 1402/11/06**
Update count: **0**

Registration date
2024-01-26, 1402/11/06

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
2024-02-20, 1402/12/01

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Determination of effect of Ursodeoxycholic acid on gallstone in pateint undergoing bariatric surgery while having asymptomatic gallstone

Public title

Evaluation of Ursodeoxycholic acid effect on gallstone in pateint undergoing bariatric surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria include morbidly obese patients who are candidates for bariatric surgery (Sleeve, Classic Bypass or OAGB) and have asymptomatic gallstones.

Exclusion criteria:

Patients with symptomatic gallstones Impaired liver tests History of previous bariatric surgery History of taking Ursodeoxycholic acid during the last month of pregnancy history of taking Oral contraceptive pills (OCP) Drug and alcohol abuse Sensitivity to Ursodeoxycholic acid

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list including 60 patients is prepared using the four random blocks method. The randomization unit is individual and the randomization tool is PASS11 statistical software and is at the disposal of the statistical expert of the project (that is, the person who performs the patient allocation and in (patient assessment does not play a role). In addition to blinding, the preparation of the randomized list ensures concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study participant,radiologist(outcome evaluator) and principal researcher will be blind.Both intervention and control groups recieve completely identical tablets and they will not know about their groups. A radiologist who measures the size and number of Gallstones and principal researcher enters the results do not know about participant Group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ehtics Committee of Iran University of Medical Sciences

Street address

Fifth floor, Headquarter., Iran university of Medical Sciences., between Chamran and Sheikh Fazlollah., Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2024-01-16, 1402/10/26

Ethics committee reference number

IR.IUMS.FMD.REC.1402.406

Health conditions studied

1

Description of health condition studied

Morbid Obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

Primary outcomes

1

Description

Size of gallstones

Timepoint

Measuring the size of gallstones at the beginning of the study (before the start of the intervention) and after the completion of the ursodeoxycholic acid drug (6 months after surgery)

Method of measurement

With sonography to mm

2

Description

number of gallstones

Timepoint

Measuring the number of gallstones at the beginning of the study (before the start of the intervention) and after the completion of the ursodeoxycholic acid drug (6 months after surgery)

Method of measurement

With sonography to number

Secondary outcomes

1

Description
nausea
Timepoint
One, three and six months after surgery
Method of measurement
Examination by a doctor

2

Description
Vomitting
Timepoint
One, three and six months after surgery
Method of measurement
Examination by a doctor

3

Description
Upper abdominal pain
Timepoint
One, three and six months after surgery
Method of measurement
Examination by a doctor

4

Description
early satiety
Timepoint
One, three and six months after surgery
Method of measurement
Examination by a doctor

Intervention groups

1

Description
Intervention group: The group receiving the drug will receive UDCA capsules (Ursobil) made by the AANIDARMAN company with a dose of 300 mg every 12 hours for 6 months for free.
Category
Treatment - Drugs

2

Description
Control group: The control group also receives a placebo medicine with the same appearance as the original medicine every 12 hours for 6 months for free
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fateme Hospital
Full name of responsible person
Mohammad Kerman Saravi
Street address
Youssef Abad - Seyed Jamaluddin Asadabadi Street - 21 Street
City
Tehran
Province
Tehran
Postal code
1433933111
Phone
+98 21 8871 7272
Email
crtfatima@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran University of Medical Science., Hemmat highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 86701
Email
info@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 Kerman Saravi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Yousef Abad

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 8871 7272

Email
mkermansaravi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Kerman Saravi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
General Surgery

Street address
Yousef Abad

City
Tehran

Province
Tehran

Postal code
1433933111

Phone
+98 21 8871 7272

Email
mkermansaravi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Masoumeh Shahsavan

Position
Education Expert

Latest degree
Master

Other areas of specialty/work
Epidemiology

Street address
Habib Zadegan

City
Tehran

Province
Tehran

Postal code
1458886944

Phone
+98 21 3689 1809

Email
mashahsavan@yahoo.com

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