

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

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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		Secondary Ids	
		empty	
Public title	Evaluation of Ursodeoxycholic acid effect on gallstone in pateint undergoing bariatric surgery	Ethics committees	
Purpose	Treatment	1	
Inclusion/Exclusion criteria		Ethics committee	
Inclusion criteria:	Inclusion criteria include morbidly obese patients who are candidates for bariatric surgery (Sleeve, Classic Bypass or OAGB) and have asymptomatic gallstones.	Name of ethics committee	Ehtics Committee of Iran University of Medical Sciences
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	Street address	Fifth floor, Headquarter., Iran university of Medical Sciences., between Chamran and Sheikh Fazlollah., Hemmat highway
Age	From 18 years old to 75 years old	City	Tehran
Gender	Both	Province	Tehran
Phase	1	Postal code	1449614535
Groups that have been masked	- Participant - Investigator - Outcome assessor	Approval date	2024-01-16, 1402/10/26
Sample size	Target sample size: 60	Ethics committee reference number	IR.IUMS.FMD.REC.1402.406
Randomization (investigator's opinion)	Randomized	Health conditions studied	
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.	1	
Blinding (investigator's opinion)	Double blinded	Description of health condition studied	Morbid Obesity
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.	ICD-10 code	E66.01
Placebo	Used	ICD-10 code description	Morbid (severe) obesity due to excess calories
Assignment	Parallel	Primary outcomes	
Other design features		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	

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

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Youssef Abad - Seyed Jamaluddin Asadabadi Street - 21 Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Mohammad Kerman Saravi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Postal code

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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