Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Combined and Individual Effects of Ursodeoxycholic Acid (UDCA) and Atorvastatin on Gallstone Prevention After Bariatric Surgery: a 2^2 factorial triple-blinded randomised controlled trial

Protocol summary

Study aim

-Determining and comparing the incidence of gallstone formation up to 6 and 12 months after bariatric surgery in atorstatin and UDCA (ursodeoxycholic acid) treatment groups, combined and separately, and the placebo group -Determining and comparing the incidence of stone-related complications and side effects up to 6 and 12 months after bariatric surgery in atorstatin and UDCA combined and separate treatment groups and the placebo group -Determination and comparison of the average changes of liver, kidney, thyroid function tests and lipid profiles during two weeks, 6 and 12 months after bariatric surgery in atorstatin and UDCA combined and separate treatment groups and the placebo group

Design

A randomized, three-blind, placebo-controlled clinical trial with four parallel arms (2^2 factorial design)

Settings and conduct

The study will be conducted in several bariatric centers of Imam Khomeini and Shariati hospital complex (educational-government) and Erfan hospital (private). The patient, surgeon and radiologist and data analyst will be blinded to the intervention group.

Participants/Inclusion and exclusion criteria

The inclusion criteria include: Adults aged 18 to 65 years who are candidates for RYGB or sleeve gastrectomy (those with a BMI higher than 35 kg/m2 or those with a BMI higher than 30 kg/m2 and with obesity-related diseases) Exclusion criteria include: History of bariatric or gallbladder surgery. Those for whom gallstones have been identified in the preoperative ultrasound

Intervention groups

Patients will be divided into four groups receiving different treatments: atorvastatin and UDCA, atorvastatin and UDCA-like placebo, atorvastatin-like placebo and UDCA, and atorvastatin-like placebo and UDCA-like placebo.

Main outcome variables

Gallstone formation, stone-related complications, type of bariatric surgery, quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240724062536N1**
Registration date: **2025-02-28, 1403/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-28, 1403/12/10**
Update count: **0**

Registration date

2025-02-28, 1403/12/10

Registrant information

Name

Erfan Shirmohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3440 3475

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-06, 1403/07/15

Expected recruitment end date

2025-03-15, 1403/12/25

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Combined and Individual Effects of Ursodeoxycholic Acid (UDCA) and Atorvastatin on Gallstone Prevention After Bariatric Surgery: a 2^2 factorial triple-blinded randomised controlled trial

Public title
Ursodeoxycholic Acid (UDCA) and Atorvastatin Efficacy on Gallstone Prevention After Bariatric Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18 to 65 years who are candidates for RYGB or sleeve gastrectomy (those with a BMI higher than 35 kg/m2 or those with a BMI higher than 30 kg/m2 and with obesity-related diseases) People with a healthy gallbladder No contraindications for UDCA or atorvastatin. Willingness and ability to provide written informed consent. Individuals without severe comorbidities that could complicate surgery or recovery.
Exclusion criteria:
Those for whom gallstones have been identified in the preoperative ultrasound History of bariatric or gallbladder surgery. Use of drugs that interfere with UDCA or atorvastatin (cholestyramine, colestipol, aluminum-containing antacids, and estrogens) and intestinal conditions that interfere with the absorption of these drugs. Current use of contraindications to lipid-lowering medications (including HIV protease inhibitors such as ritonavir, warfarin, cyclosporine, verapamil, and amiodarone) People with intolerance or allergy to UDCA or atorvastatin Pregnancy or breastfeeding.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **308**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are assigned to treatment groups using a stratified block randomization (block size 8) method using Microsoft Excel software. Treatment groups are first identified in blocks of 8, and then a random number is generated for each patient using the RAND() function. These random values are used to randomly sort the blocks. Patients are assigned sequentially from the randomized list in the order of enrollment to maintain a balance in the number of patients in each group. Treatment groups include UDCA + atorvastatin, UDCA alone, atorvastatin alone, and placebo. Technically, patient allocation is performed at the time of enrollment using the INDEX() function, which assigns a treatment group to a new patient from the randomized list. This method ensures that patients are distributed fairly and without bias to the treatment groups. The study is designed as a triple-blind design, meaning that the patient, the evaluating physician, and the data analyst are unaware of the assigned treatment group. This method in Excel allows for simple and reproducible randomization without the need for complex statistical software. In Excel, randomization is performed by combining the RAND(), SORT(), and INDEX() functions. First, RAND() generates a random number between 0 and 1 for each patient. Then, using the Sort function based on the RAND() values, the order of the patients is randomly changed. After sorting, the INDEX() function is used to assign new patients to one of the treatment groups in the order they arrive. This method is considered a practical and reliable solution for randomization in clinical studies due to its simplicity, high accuracy, and control of balance between groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Patients will not know about the type of medicine provided. During each visit, the doctors will not know which type of medical intervention the patient is undergoing, and the radiologist who is responsible for the 6- and 12-month ultrasound is also unaware of the patient's group. The data analyzer will also receive a list of patient groups (1 to 4) in a protected Excel cloud file without ID and specific group type.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences - Imam Khomeini Hospital, Tehran
Street address
Keshavarz Boulevard, Imam Khomeini Hospital, Tehran, Ethics Committee, Research Unit
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱

Approval date
2024-12-30, 1403/10/10
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.429

Health conditions studied

1

Description of health condition studied
Gallstones
ICD-10 code
K80.2
ICD-10 code description
Calculus of gallbladder without cholecystitis

Primary outcomes

1

Description
Gallstones incidence
Timepoint
At 6 month and 1 year
Method of measurement
Sonography

Secondary outcomes

1

Description
Cholecystitis
Timepoint
6 month and 1 year
Method of measurement
History and Sonography

Intervention groups

1

Description
Intervention group: UDCA only,Ursobil at a dose of 600 twice a day and a placebo tablet
Category
Treatment - Drugs

2

Description
Intervention group: Atorvastatin, 40 mg once daily and two placebo tablets
Category
Treatment - Drugs

3

Description
Intervention group: Atorvastatin + UDCA, in the form of two 300 mg Ursobil tablets (600 in total) and 1 40 mg Atorvastatin tablet
Category
Treatment - Drugs

4

Description
Control group: Placebo, in the form of three tablets per day. Placebo drugs are prepared from inactive substances with no therapeutic effect and are similar in shape, color, size, and packaging to the drugs used in the treatment groups to prevent disclosure of the treatment group. Placebo is being manufactured by the Department of Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences, and its physical characteristics are designed in accordance with clinical study standards.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Cmplx Tehran
Full name of responsible person
Erfan Shirmohamadi
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2

Recruitment center
Name of recruitment center
Erfan Niyayesh Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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+98 21 8858 7400
Email
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Erfan Shirmohamadi
Position
Medical Student
Latest degree
A Level or less
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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
Data would be shared after de-identification of shared patients.
When the data will become available and for how long
Immediately after the results of the final phase of the trial were published.
To whom data/document is available
All researchers provided an acceptable explanation
Under which criteria data/document could be used
Any use of data within the framework of the request submitted to our team will be acceptable.
From where data/document is obtainable
Researchers should contact the corresponding author to access the data. The author's email and contact information are listed at the beginning of this form. shirmohamadi.erf@gmail.com
What processes are involved for a request to access data/document
1. Submission of a complete request for motivation letter and the type of analysis in question on the trial database
2. Providing complete information about the location of the secondary study and the group along with the details of the people involved in the study After studying the necessary information and requesting more information, the group will notify the applicant of the decision within 3 month.
Comments