

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Combined and Individual Effects of Ursodeoxycholic Acid (UDCA) and Atorvastatin on Gallstone Prevention After Bariatric Surgery: a 2² 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 (2² 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

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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 2² 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

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Web page address**2****Recruitment center****Name of recruitment center**

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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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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

Other areas of specialty/work

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Position

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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