

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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 agenesis 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

###### Email address

besharat.sara@sbm.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/m<sup>2</sup> in healthy people and more than 35 kg/m<sup>2</sup> with comorbidity)

**Exclusion criteria:**

- patient with past history of cholecystectomy - patient with gallbladder agenesis -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,

Saadat Abad  
**City**  
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**Province**  
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1998734383  
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+98 21 2207 4087  
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+98 21 2207 4101  
**Email**  
modarres@sbmu.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seyyed Ali Ziai  
**Street address**  
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

Nasser Malekpour Alamdari

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

General Surgery

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Shahid Beheshti University of Medical Sciences, Arabi street, Velenjak.

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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