

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Comparing the safety and efficacy of the Ursodeoxycolic acid (Cholicray) and Ursophar in Patients with fatty liver disease and biliary disorders

#### Protocol summary

##### Study aim

Determining the side effects, comparing the safety and efficacy of Cholicray and Ursophar drug

##### Design

Two arm parallel group trial, double blind, randomized, phase 2 on 70 patient. block randomization method will be used.

##### Settings and conduct

This study will be conducted in Baqiyatallah Hospital in Tehran. Patients will take Cholicray or Ursophar medicine for three months, and the variables of the study will be measured before the beginning and after the end. Patients and caregivers will be unaware of their placement in the intervention or control group

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Age above 18 years, consent to participate in the study, Presence of liver or biliary disorders such as fatty liver, cholangitis, Primary biliary cirrhosis, Calculus of bile duct. exclusion criteria: pregnancy

##### Intervention groups

The study has two groups in which, the intervention group will use Ursodeoxycolic acid (Cholicray)( 13to15 milligram per kilogram per day/ Reyhaneh Pharmaceutical Company ) drug and in the control group patients will take Ursophar drugs ( 13to15 milligram per kilogram per day/ Koushan Pharmed pharmaceutical company) within 3 months.

##### Main outcome variables

AST (aspartate aminotransferase), ALT(alanine transaminase), and ALK.P(Alkaline phosphatase) and possible side effects in these patients such as skin rash, itching, jaundice, nausea, vomiting, vertigo

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210914052480N3**

Registration date: **2023-08-05, 1402/05/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-05, 1402/05/14**

Update count: **0**

##### Registration date

2023-08-05, 1402/05/14

##### Registrant information

###### Name

Alireza Soleymanitabar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8755 4364

###### Email address

stu.soleymanitabar@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-09, 1402/01/20

##### Expected recruitment end date

2024-02-09, 1402/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the safety and efficacy of the Ursodeoxycolic acid (Cholicray) and Ursophar in Patients with fatty liver disease and biliary disorders

##### Public title

Investigation of the safety of Ursodeoxycholic acid (Cholicray)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

above 18 years old  
Consent to participate in the study  
Presence of liver or biliary disorders such as fatty liver, cholangitis, Primary biliary cirrhosis, Calculus of bile duct.

#### Exclusion criteria:

pregnancy

### Age

From 18 years old

### Gender

Both

### Phase

2

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: 70

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block Randomization would be done with 4 units blocks and by Using pre-determined blocks by table of random numbers, we will randomly assign individuals to two groups and prescribe the corresponding medication. Each medication will be assigned a unique code that the therapist will not be aware of, only the researchers will know the order.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Study participants will first learn about the two drugs used in the intervention and control groups. Then they will receive a medicine can with a specific code, so the patient and the clinical caregiver will not know that they are in which one of the study groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Baqiyatallah educational and medical center

##### Street address

Research center; Baqiyatallah University of Medical Sciences, Sheykh-Bahaei intersection, Mollasadra st. Vanak sq, Tehran

### City

Tehran

### Province

Tehran

### Postal code

1435916471

### Approval date

2023-02-27, 1401/12/08

### Ethics committee reference number

IR.BMSU.BAQ.REC.1401.127

## Health conditions studied

### 1

#### Description of health condition studied

Primary biliary cirrhosis

#### ICD-10 code

K74.3

#### ICD-10 code description

Primary biliary cirrhosis

### 2

#### Description of health condition studied

Fatty (change of) liver, not elsewhere classified(Nonalcoholic fatty liver disease [NAFLD])

#### ICD-10 code

K76.0

#### ICD-10 code description

Fatty (change of) liver, not elsewhere classified

### 3

#### Description of health condition studied

Calculus of bile duct

#### ICD-10 code

K80.3

#### ICD-10 code description

Calculus of bile duct with cholangitis

### 4

#### Description of health condition studied

cholangitis

#### ICD-10 code

K83.0

#### ICD-10 code description

Cholangitis

## Primary outcomes

### 1

#### Description

Change in sense of taste

#### Timepoint

Before the intervention and after the intervention

#### Method of measurement

asking the patient and filling the checklist

## 2

### **Description**

Alanine transaminase(ALT)

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Mindray BS-800 Bio-Chemistry Analyzer

## 3

### **Description**

skin rashes

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 4

### **Description**

eye dryness

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 5

### **Description**

Chest pain

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 6

### **Description**

muscle pain

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 7

### **Description**

Frequent urination

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 8

### **Description**

Total Bilirubin test

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Mindray BS-800 Bio-Chemistry Analyzer

## 9

### **Description**

Alkaline phosphatase(ALP)

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Mindray BS-800 Bio-Chemistry Analyzer

## 10

### **Description**

Aspartate transaminase(AST)

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Mindray BS-800 Bio-Chemistry Analyzer

## 11

### **Description**

Direct Bilirubin test

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Mindray BS-800 Bio-Chemistry Analyzer

## 12

### **Description**

skin itching

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 13

### **Description**

skin dryness

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 14

### **Description**

Skin redness and hives

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## 15

### **Description**

Nausea

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **16**

### **Description**

Vomiting

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **17**

### **Description**

heartburn

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **18**

### **Description**

flatulence

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **19**

### **Description**

diarrhea

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **20**

### **Description**

Cramps

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **21**

### **Description**

constipation

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **22**

### **Description**

early satiety

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **23**

### **Description**

blurred vision

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **24**

### **Description**

strabismus

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **25**

### **Description**

eye pain

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **26**

### **Description**

eye redness

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **27**

### **Description**

Kidney pain

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **28**

### **Description**

dysuria

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

## **29**

### **Description**

Urine color change

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

asking the patient and filling the checklist

### **30**

**Description**

Dyspnea

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **31**

**Description**

Frequent cough

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **32**

**Description**

sputum

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **33**

**Description**

headache

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **34**

**Description**

vertigo

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **35**

**Description**

dizziness

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **36**

**Description**

sleep disorder

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **37**

**Description**

Pain radiating to the limbs

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **38**

**Description**

hearing problems

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **39**

**Description**

olfactory disorder

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

### **40**

**Description**

tingling

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

asking the patient and filling the checklist

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

**Description**

Intervention group: The group receiving URSODEOXYCHOLIC ACID CAPSULE ORAL with a standard dose (13to15 milligram per kilogram per day) or CHOLICRAY (Rayhaneh Pharmaceutical Company) for 3 months.

**Category**

Treatment - Drugs

### **2**

**Description**

Control group: The group receiving Ursophar (Koushan Pharmed pharmaceutical company) with a standard dose (13to15 milligram per kilogram per day) for 3 months.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Baqiyatallah Hospital

**Full name of responsible person**

Mohammad Ali Abyazi

**Street address**

Gastroenterology Clinic, Baqiyat Allah Hospital,  
Sheykh-Bahaei intersection, Mollasadra st, Vanak sq,  
Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8805 0435

**Email**

yashar862@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Reyhaneh Pharmaceutical Company

**Full name of responsible person**

Naghmeh Piroozi

**Street address**

Second floor, No. 5, Parvaneh St., Jalal Al Ahmad St.,  
Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1439915481

**Phone**

+98 31 3859 7203

**Email**

info@rayhanehpharma.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Reyhaneh Pharmaceutical Company

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

## Type of organization providing the funding

Industry

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mohammad Heiat

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biology

**Street address**

Gastroenterology Clinic, Baqiyat Allah Hospital,  
Sheykh-Bahaei intersection, Mollasadra st. Vanak  
Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8755 5250

**Email**

mohamad.heiat@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Abyazi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Gastroenterology Clinic, Baqiyatallah Hospital,  
Sheykh-Bahaei intersection, Mollasadra st. Vanak sq,  
Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8755 5250

**Email**

yashar862@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Alireza Soleymanitabar

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Students Research Committee, Baqiyatallah  
University of Medical Sciences, Sheykh-Bahaei  
intersection, Mollasadra St., Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1435915371

**Phone**

+98 21 8755 4364

**Fax****Email**

stu.soleymanitabar@bmsu.ac.ir

## 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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

the data would be sent without any personal information of patients

**When the data will become available and for how long**

after data gathering

**To whom data/document is available**

Only people with relevant permissions to use confidential information

**Under which criteria data/document could be used**

The data can be used for statistical analysis and re-examination

**From where data/document is obtainable**

Mohamad Heiat Phone no. +98 936 687 6929

**What processes are involved for a request to access data/document**

After calling or sending an email, the data will be sent if the applicant is valid

**Comments**