

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

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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

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Province

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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.

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Province

Tehran

Postal code

1435915371

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+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