

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparative study of the effect of the combined method ursodeoxycholic acid and fenofibrate with single-drug method ursodeoxycholic acid on clinical features and Laboratory tests in primary sclerosing cholangitis.

#### Protocol summary

##### Study aim

Comparison of the Effects of ursodeoxycolic acid and fenofibrate and ursodeoxycolic acid plus placebo on clinical features and Laboratory tests

##### Design

double-blind randomized clinical trial, control group

##### Settings and conduct

This study will be carried out in Gastrointestinal and Liver disease research center. The intervention group will be treated with 300 mg ursodeoxycolic acid daily 8 to 10 mg per kg body weight divided into two to three doses and 200 mg fenofibrate b.i.d dose for 12 weeks. Control group will be treated with 300 mg ursodeoxycolic acid daily 8 to 10 mg per kg body weight divided into two to three doses and 200 mg placebo b.i.d dose for 12 weeks.

##### Participants/Inclusion and exclusion criteria

1-Confirmation of disease by expert physician with ERCP or MERCPC 2- Patients with age 20 or more and below 70 years 3-patients with ALP of 400IU/L or over Exclusion criteria:1- Secondary sclerosing cholangitis 2-Severe jaundice( total bilirubin 5 ULN), AST or ALT 10 ULN or severe renal disorders (creatinine 1.5 ULN or under hemodialysis)

##### Intervention groups

This study has 2 groups. every 2 groups will be treated with 300 mg ursodeoxycolic acid. The first group will receive ursodeoxycolic acid plus fenofibrate for 12 weeks and will be considered as an intervention group. The second group will receive ursodeoxycolic acid plus placebo for 12 weeks and will be considered as a control group regimen

##### Main outcome variables

Treatment of patients with primary sclerosing cholangitis.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080901001155N31**

Registration date: **2019-05-17, 1398/02/27**

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

Last update: **2019-05-17, 1398/02/27**

Update count: **0**

##### Registration date

2019-05-17, 1398/02/27

##### Registrant information

##### Name

Farahnaz Joukar

##### Name of organization / entity

Guilan University of Medical Sciences,  
Gastrointestinal and liver disease Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1553 5116

##### Email address

info@glrc.org

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-06, 1398/01/17

##### Expected recruitment end date

2020-04-05, 1399/01/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of the effect of the combined method ursodeoxycholic acid and fenofibrate with single-drug method ursodeoxycholic acid on clinical features and Laboratory tests in primary sclerosing cholangitis.

**Public title**

The efficacy of Ursudoxicolic acid combination with fenofibrate in patients with primary sclerosing cholangitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with PSC disease confirmed by a specialist using ERCP or MRCP.

**Exclusion criteria:****Age**From **20 years** old to **70 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**Target sample size: **30****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment in this study will be in the form of block Randomization. In this way, the number of people in the two groups A and B is the same throughout the study period

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This double-blind study will be conducted. The first part of the blinding is for patients who do not know which drug (A group and B group) they received. The next section is about the person who asked for the medication to be given to patients who are not A or B drug.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee**

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences.

**Street address**

Research and Technology Deputy ,Shaheed Beheshti street,Gaz square

**City**

Rasht

**Province**

Guilan

**Postal code**

41448956655

**Approval date**

2019-02-23, 1397/12/04

**Ethics committee reference number**

IR.GUMS.REC.1397.457

**Health conditions studied****1****Description of health condition studied**

primary scleroding cholangitis

**ICD-10 code**

80.5

**ICD-10 code description**

K80-K87

**Primary outcomes****1****Description**

primary scleroding cholangitis treatment

**Timepoint**

Before starting treatment, weeks 6, 12,18,24,30,36 from the point of view ALT, AST, ALP, Gamma- Glutamyl transpeptidase, Bilirubin Total, Bilirubin Direct,Albumin and Prothrombin and weeks 12,24,36 from the point of view TG, Total-Cholestrol and LDL.

**Method of measurement**

Blood test

**Secondary outcomes****1****Description**

Response to treatment and possible side effect

**Timepoint**

Weeks 6, 12,18,24,30,36 from the point of view ALT, AST, ALP,Gamma-Glutamyl transpeptidase,Bilirubin Total,Bilirubin Direct,Albumin and Protrombin and weeks 12,24,36 from the point of view TG, Total-Cholestrol and LDL

**Method of measurement**

Blood test

**Intervention groups**

## 1

### Description

Intervention group: UDCA drug dose of 300 mg daily 8 to 10 mg per kilogram of body weight divided into two to three doses by So.Se.Pharm plus fenofibrate dose of 200 mg b.i.d for 12 weeks by Sobhan.

### Category

Treatment - Drugs

## 2

### Description

Control group: UDCA drug dose of 300 mg daily 8 to 10 mg per kilogram of body weight divided into two to three doses by So.Se.Pharm plus placebo dose of 200 mg b.i.d for 12 weeks by Sobhan.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

مرکز تحقیقات بیماریهای گوارش و کبد گیلان

#### Full name of responsible person

دکتر فرحناز جوکار

#### Street address

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospital, Sardare Jangal Avenue

#### City

Rasht

#### Province

Guilan

#### Postal code

41448956655

#### Phone

+98 13 3351 9248

#### Fax

+98 13 3353 4951

#### Email

farajov@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

دکتر میر سعید عطارچی

#### Street address

Sadati st, Namjoo st

#### City

Rasht

#### Province

Guilan

#### Postal code

4144666949

### Phone

+98 13 3336 2772

### Email

msattarchi@yahoo.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Rasht 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

Rasht University of Medical Sciences

#### Full name of responsible person

دکتر فرحناز جوکار

#### Position

معاون مرکز تحقیقات بیماریهای گوارش و کبد

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Epidemiology

#### Street address

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospital, Sardare Jangal Avenue

#### City

Rasht

#### Province

Guilan

#### Postal code

41448956655

#### Phone

+98 13 3353 5116

#### Email

farajov@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Rasht University of Medical Sciences

#### Full name of responsible person

دکتر فریبرز منصور قناعی

#### Position

استاد-فوق تخصص بیماریهای گوارش و کبد

#### Latest degree

Subspecialist

**Other areas of specialty/work**

Others

**Street address**

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospital, Sardare Jangal Avenue

**City**

Rasht

**Province**

Guilan

**Postal code**

41448956655

**Phone**

+98 13 3353 5116

**Email**

ghanaie@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Sara Yeganeh

**Position**

Master of Microbiology

**Latest degree**

Master

**Other areas of specialty/work**

Microbiology

**Street address**

Gastrointestinal and Liver Diseases Research Center,  
Razi Hospital, Sardare Jangal Avenue

**City**

Rasht

**Province**

Guilan

**Postal code**

41448956655

**Phone**

+98 13 3353 5116

**Email**

Yeganeh\_sara6@yahoo.com

**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**

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 main outcome of this study, which is to treat primary sclerosing cholangitis, reduce clinical signs and laboratory improvements, will be made available to the general public.

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

A year after printing results

**To whom data/document is available**

Researchers at relevant research centers, universities, and related doctors

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

In this case, the decision has not yet been taken

**From where data/document is obtainable**

Sara yeganeh Gastrointestinal and Liver Diseases Research Center, Razi hospital, Rasht 00981333535116 955655-41448 Yeganeh\_sara6@yahoo.com

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

At the outset, the applicant will email and complete his or her full introduction of the organization and the purpose of obtaining this data and will request the relevant documents or files. Subsequently, the data files will be made available to the applicant within the time period stated by the relevant investigator

**Comments**