

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 ursodeoxycholic acid and fenofibrate and ursodeoxycholic 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 ursodeoxycholic 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 ursodeoxycholic 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 ursodeoxycholic acid. The first group will receive ursodeoxycholic acid plus fenofibrate for 12 weeks and will be considered as an intervention group. The second group will receive ursodeoxycholic 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)

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+98 13 1553 5116

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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 Ursodeoxycholic 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

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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

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Guilan

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Phone

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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

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Email

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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

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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

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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

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