

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of Fenofibrate on the Clinical Outcome of primary Sclerosing Cholangitis

Protocol summary

Study aim

The effect of fenofibrate on the clinical outcome of primary sclerosing cholangitis

Design

Clinical trial include 2 arm parallel (intervention group and control group), double blind, randomized in 3rd phase on 30 cases on primary sclerosing cholangitis

Settings and conduct

Selection of 30 patients with primary sclerosing cholangitis in terms of entry and exit indicators by a fixed person to whom the identity card details have not been transferred. Only patients' numbers and medication packages will be provided to them. It will be done by lottery. It will be available to the researcher in both blind and random directions

Participants/Inclusion and exclusion criteria

chronic cholestatic liver disease for 6 month, alkaline phosphatase serum level x1.5 ULN, imaging or histopathologic finding that confirmed disease

Intervention groups

Patients who have primary sclerosing cholangitis, Half of them as interventional group receive tab fenofibrate 200mg daily and others as controller group receive placebo capsule.

Main outcome variables

Pruritis, Alkaline Phosphatase serum level, Bilirubin serum level, Mayo risk score

General information

Reason for update

control group, placebo intervention

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047225N1**

Registration date: **2020-06-02, 1399/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-28, 1400/11/08**

Update count: **1**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

mozhde mosala

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4443 8262

Email address

mohd109@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-03, 1399/02/14

Expected recruitment end date

2020-11-04, 1399/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Fenofibrate on the Clinical Outcome of primary Sclerosing Cholangitis

Public title

Fenofibrate in PSC

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

chronic cholestatic liver disease for at least 6 month

alkaline phosphatase serum level atleast 1.5x upper limit normal multi focal dilation and stricture in intra/extra hepatic billiary ducts on MRCP or liver biopsy confirmed PSC (fibrosing cholangitis, ductopenia, peei portal inflammation or biliary fibrosis)

Exclusion criteria:

concurrent advanced malignancy or severe cardiopulmonary disease with less than 2 years survival inflammatory intestinal diseasethat need medical therapy during 3 month from begining (except miantenance therapy with 5-ASA) candidate for liver transplant and survival less than 80% in 2 years according to MAYO risk score portal hypertension complicatin such as variceal bleeding ascitis liver encephalopathy pregnancy or breast feeding age under 18 years or above 75 years other liver disease diagonosis sugc as chronic alcoholic livera disease, B or C hepatitis, auto immune hepatitis, primary biliary cirrosis, hemochromatosis, wilson disease, congenital biliary disease or cholangiocarcinoma previous biliary stone or ductal manipulation, cholecystectomy or other biliary drainage before PSC confirmed ascending biliary cholangitis need more than twice a years admission patient who di not allow fenofibrate allergy or intolerance or side effects concurrent use of local or systemic anti-itch agents such as anti histamins

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial we assumed minimum number of cases is 30. for random selection, patients were numbered according to entrance respectively. RV.uniform function in SPSS was executed, if the output was more than 0.5 patient will categorize as group 1 (intervention), otherwise in group 2 (control). if number of each group reach 15 cases, no more cases will be added to that group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The selection of patients in terms of inclusion and exclusion criteria in a targeted manner and by a fixed person to whom th eidentify card details of individuals have not been transferred and only the numbers of patients and drug package will be provided to them, will be done by lottery and given to the researcher.

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, koodakyar street, Daneshjoo blvd, Velenjak, Shahid Chamran Highway, Tehran, Iran

City

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1985717443

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.SBMU.MSP.REC.1398.198

Health conditions studied

1

Description of health condition studied

primary sclerosing cholangitis disease

ICD-10 code

K74.1

ICD-10 code description

Hepatic sclerosis

Primary outcomes

1

Description

Serum Alkaline Phosphatase

Timepoint

Measurement of Serum Alkaline APhosphatase at base and after 6 month Therapy with Fenofibrate

Method of measurement

Chemistry Laboratory

Secondary outcomes

1

Description

Serum level of Billirubin

Timepoint

At base and after 6 month Therapy with Fenofibrate

Method of measurement

Chemistry Laboratory

2

Description

Pruritis

Timepoint

At base and after 6 month Therapy with Fenofibrate

Method of measurement

Questionary

3

Description

Mayo Risk Score

Timepoint

At base and after 6 month Therapy with Fenofibrate

Method of measurement

Mayo Risk Score system

Intervention groups

1

Description

Intervention group: Fifteen patients aged 18 to 75 years with primary sclerosing cholangitis are initially assessed in terms of liver enzyme levels, pruritus, and Mayo risk score. Patients then take 200 mg of phenofibrate tablets daily for 6 months in addition to the underlying disease medications (according to the study entry and exit indices). At the end of the sixth month, patients will be re-examined for liver enzymes, itching, and Mayo risk scores. Data analysis will be performed using SPSS version 24 software. $p > 0.05$ is considered a significant level.

Category

Treatment - Drugs

2

Description

Control group: Control group: 15 patients aged 18 to 75 years with primary sclerosing cholangitis are initially examined for liver enzyme levels, pruritus, and Mayo score. Patients receive background medications and placebo (a capsul same as fenofibrate) for 6 months. At the end of the sixth month, patients will be re-examined for liver enzymes, itching, and Mayo score, and compared with the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

institute of gastroenterology and liver disease

Full name of responsible person

Dr. Behzad Hatami

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50m after Taleghani Hospital, Arabi street, Yaman street, Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President Research and Innovation

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Web page address

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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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Phone**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 further information

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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