Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 parimary sclerosing cholangitis
Design
Clinical trial include 2 arm parallel (intervention group and control group), double blind, randomized in 3rd phase on 30 cases on primay 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 recieve tab fenofibrate 200mg daily and others as controller group recieve placebo capsule.
Main outcome variables
Pruritis, Alkalin 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 atleast 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 inlammatory 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 sucg 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, cholecycstectomy 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

Tehran

Province

Tehran

Postal code

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
Street address
50m after Taleghani Hospital, Arabi street, Yaman street, Chamran Highway
City
تهران
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2526
Email
mohd109@gmail.com
Web page address
http://rigld.sbmu.ac.ir

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
Street address
Floor 5th, Setad 2 uilding, Shahid Beheshtin University of Medical Science, Arabi street, Yaman street, Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 2243 9781
Fax
+98 21 2243 9981
Email
Mpajouhesh@sbmu.ac.ir
Web page address
https://retech.sbmu.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mozhde Mosala
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 35, east Golestan ave, Ashrafi Esfahani hw, south Pounak
City
Tehran
Province
Tehran
Postal code
1469617491
Phone
+98 21 4443 8262
Fax
Email
mohd109@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mozhde Mosala
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 35, east Golestan ave, Ashrafi Esfahani hw, south Pounak
City
Tehran
Province
Tehran
Postal code
1469617491
Phone
+98 21 4443 8262
Fax
Email
mohd109@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mozhde Mosala
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
No 35, east Golestan ave, Ashrafi Esfahani hw, south Pounak
City
Tehran
Province
Tehran
Postal code
1469617491
Phone
+98 21 4443 8262
Fax
Email
mohd109@gmail.com

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