# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigation the effect of Inositol in patients with Primary Sclerosing Cholangitis

### Protocol summary


**Study aim**
Investigation the effect of inositol on Primary Sclerosing Cholangitis patients

**Design**
Clinical trial with parallel groups, double-blind, randomized, phase 3 on 100 patients. Patients will be divided into two groups in random blocks.

**Settings and conduct**
In this double blinded study, patients included in the study will be taking a disease history and performing a physical examination, blood samples will be collected and sent for laboratory evaluation, measuring AST, ALT,ALKP, Albumin and Bilirubin (total and direct). Then patients were randomly assigned in a 1:1 ratio to receive either a placebo or inositol supplement (800 mg) in identical form and packaging, which will be taken for 3 months. after that the patients will be reevaluated.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: cholestatic liver disease for at least 6 months, serum alkaline phosphatase level 1.5 times the upper limit of normal, and evidence of multifocal dilatation and stenosis of intrahepatic bile ducts, extrahepatic bile ducts. Exclusion criteria: cancer, cardiopulmonary disease; Anticipated liver transplant; cirrhosis, portal hypertension; pregnancy and nursing mothers; concomitant liver diseases, gallstones, recurrent ascending cholangitis, sensitivity to inositol or a history of severe side effects; Kidney failure

**Intervention groups**
The first group received 800 mg inositol supplement. The second group received placebo

**Main outcome variables**
normal level of AST, ALT, Albumin and Bilirubin and also 50% reduction in ALKP, alleviation of and prutrius, a decline in the Mayo Risk Score of patients.


### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220417054557N2**
Registration date: **2024-03-06, 1402/12/16**
Registration timing: **prospective**

Last update: **2024-03-06, 1402/12/16**
Update count: **0**

**Registration date**
2024-03-06, 1402/12/16


**Registrant information**
**Name**
Shabnam Shahrokh
**Name of organization / entity**
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-03-10, 1402/12/20

**Expected recruitment end date**
2024-05-30, 1403/03/10

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigation the effect of Inositol in patients with Primary Sclerosing Cholangitis

**Public title**
The effect of inositol on the improvement of primary sclerosing cholangitis patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
cholestatic liver disease for at least 6 months serum alkaline phosphatase levels 1.5 times the normal upper limit
**Exclusion criteria:**
co-existing liver diseases such as alcoholic liver disease and NAFLD, autoimmune hepatitis, chronic B or C hepatitis, PBC, hemochromatosis, Wilson's disease, congenital biliary disease, and cholangiocarcinoma
**Age**
From **18 years** old to **75 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are assigned to two groups using the random block method. The number of blocks will be 22 and in each block two, four, or six patients according to the order of entry are studied. Random allocation of blocks of patients to two groups receiving Inositol and receiving placebo It will be done through Sealed Envelope online software. Concerning the site https://www.sealedenvelope.com/simple-randomiser/v1/lists By specifying the total number of samples, and the number of possible samples in each random block (2, 4 and 6 patients), randomization is performed by online software. For example, like the following output: block identifier block size sequence within block treatment 1 2 1 Group B 1 2 2 Group A 2 4 1 Group A 2 4 2 Group B 2 4 3 Group B 2 4 4 Group A 3 2 1 Group A 3 2 2 Group B ... which is the block number, the number of patients in the block, and the random assignment of each patient (with the corresponding number) to the treatment group. The randomized list of blocks will be placed in sealed envelopes and will be provided to the gastroenterologist on a daily basis.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Participants do not know whether they are receiving inositol or placebo. Also, to prevent exploitation, the researcher investigating the results is unaware of the allocation of the groups.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee in Biomedical Research, Gastroenterology and Liver Research Institute, Shahid Behes
**Street address**
Arabi street, Velenjak
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**Province**
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**Postal code**
۱۴۱۱۷۱۳۱۳۵
**Approval date**
2024-02-07, 1402/11/18
**Ethics committee reference number**
IR.SBMU.RIGLD.REC.1402.023

## Health conditions studied

### 1

**Description of health condition studied**
Primary Sclerosing Cholangitis
**ICD-10 code**
K83.1
**ICD-10 code description**
Obstruction of bile duct

## Primary outcomes

### 1

**Description**
alanine transaminase
**Timepoint**
before intervention and 3 month later
**Method of measurement**
blood test

### 2

**Description**
aspartate aminotransferase
**Timepoint**
before intervention and 3 month later
**Method of measurement**
blood test

### 3

**Description**
Albumin
**Timepoint**
before intervention and 3 month later
**Method of measurement**
blood test

### 4

**Description**
Bilirubin
**Timepoint**
before intervention and 3 month later
**Method of measurement**
blood test

### 5

**Description**
Alkaline Phosphatase
**Timepoint**
before intervention and 3 month later
**Method of measurement**
blood test

### 6

**Description**
alleviation of prutrius
**Timepoint**
before intervention and 3 month later
**Method of measurement**
physical examination

## Secondary outcomes

### 1

**Description**
a decline in the Mayo Risk Score of patients
**Timepoint**
before intervention and 3 months later
**Method of measurement**
Mayo Risk scale measurement

## Intervention groups

### 1

**Description**
Intervention group: Recipient of inositol supplement 800 mg/day for three months
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: placebo
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Gastroenterology and Liver Clinic of Taleghani Hospital
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

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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

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
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Elham Mortazavi
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Gastroenterology specialist assistant
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Subspecialist
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## 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**
Confidentiality and privacy
**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**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
Study protocol, statistical analysis map, study design, clinical study report will be made available
**When the data will become available and for how long**
After the publication of the article
**To whom data/document is available**
Researchers, medical students, professors
**Under which criteria data/document could be used**
If used for future research and in compliance with the principles of referencing
**From where data/document is obtainable**
Corresponding Author Dr. Shabnam Shahrokh shabnamshahrokh@gmail.com
**What processes are involved for a request to access data/document**
Send the request to the responsible author and outline the reason for the request
**Comments**