# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## The effect of probiotics consumption on liver function in Primary Sclerosing Cholangitis patients: A double-blinded randomized clinical trial

## Protocol summary

**Study aim**
Effectiveness of probiotics consumption on liver function in primary sclerosing cholangitis patients
**Design**
A double-blinded phase 3 randomized controlled trial with a parallel-group will be conducted on 44 primary sclerosing cholangitis patients.
**Settings and conduct**
The study population was adults with primary sclerosing cholangitis referred to Motahhari clinic in Shiraz. The physicians will examine the patient and evaluate the laboratory tests, and then select patients who are eligible to enter the study. The physicians referred the patients to a trained nurse who allocate patients to probiotic or placebo groups. the physicians are blinded about the probiotic and placebo groups. Patients are not informed that they are in the probiotic or placebo group. The data analyzer is also unaware of the probiotic or placebo groups.
**Participants/Inclusion and exclusion criteria**
Patients with a definitive diagnosis of primary sclerosing cholangitis and patient consent to participate in the study, and exclusion criteria: any comorbid conditions or conditions that interfere with probiotic use, and patients who are not clinically stable.
**Intervention groups**
Intervention group: the patients receive two capsules of probiotic daily for three months. Probiotic containing Lactobacillus rhamnosus, Bifidobacterium lactis, Lactobacillus casei, Bifidobacterium bruh, Lactobacillus acidophilus, Bifidobacterium longum, Lactobacillus plantarum, Bifidobacterium bifidum and Streptococcus thermophilus) (Zist takhmir Company, Tehran, Iran) . Control group: The patients receive two capsules daily, containing 100 mg of carboxymethylcellulose as a placebo, which in appearance, taste, and packaging box is similar to Femme Lactate, prepared by Zisttakhmir Co, Tehran
**Main outcome variables**
Alkaline phosphatase changes

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20200628047940N3**
Registration date: **2022-07-18, 1401/04/27**
Registration timing: **prospective**

Last update: **2022-07-18, 1401/04/27**
Update count: **0**
**Registration date**
2022-07-18, 1401/04/27

**Registrant information**
**Name**
Nasrin Motazedian
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 71 3628 1529
**Email address**
nmotazedi@sums.ac.ir

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2022-08-23, 1401/06/01
**Expected recruitment end date**
2023-03-20, 1401/12/29
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**

empty

**Scientific title**

The effect of probiotics consumption on liver function in Primary Sclerosing Cholangitis patients: A double-blinded randomized clinical trial

**Public title**

The effect of probiotics consumption on liver function

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with a definitive diagnosis of primary sclerosing cholangitis(PSC) Patients' informed consent to participate in the study

**Exclusion criteria:**

Neurological disease Chronic alcoholic fatty liver Chronic hepatitis B, C Wilson disease Hemochromatosis disease Secondary sclerosing cholangitis Primary cirrhosis of the bile ducts Benign or malignant tumor of the liver or bile ducts Peritonitis Ascites Variceal bleeding Inflammation of the brain caused by hepatitis in the past 2 months Consumption of probiotics, prebiotics, synbiotics or antibiotics 4 weeks before the start of the study High protein diet Active microbial infection Autoimmune disease or the use of immunosuppressive drugs Probability of liver transplantation in the next year based on secondary sclerosing cholangitis risk score Mayo Alpha antitrypsin deficiency Consumption of ursodeoxycholic acid Consumption of alcohol or drugs Pregnancy and lactation

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Permutation block design or quadruple blocks will be used. We assign different permutations to numbers 1 to 6 in the following order. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB Then, using the table of random numbers, we extract the numbers from the table and depending on which one of the numbers 1 to 6 comes, select each of the blocks assigned to these numbers until 11 blocks of quaternary are selected. If the numbers are zero, 7, 8, and 9, we will ignore them and continue this order to provide a complete list for the entire sample size.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A gastroenterologist and gastroenterology fellowship select patients eligible to enter the study and willing to participate. The patients will be referred to a trained nurse by introduction letter, who allocate patients to probiotic or placebo groups. The physicians will not be aware of the control and placebo groups. The nurse divide patients based on block randomization, referral time to intervention, and control group. Patients are not informed that they are in the probiotic or placebo group. The patients receive a probiotic (intervention group)or two capsules daily, containing 100 mg of carboxymethylcellulose as a placebo, which in appearance, taste, and packaging box is similar to Femme Lactate. The data analyzer is also unaware of groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Medical School, Shiraz University of Medical Sciences

**Street address**

Ethics Commitee, Shiraz School of Medicine, Imam Hossein Square Zand St., Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-45794

**Approval date**

2022-05-01, 1401/02/11

**Ethics committee reference number**

IR.SUMS.MED.REC.1401.055

## Health conditions studied

### 1

**Description of health condition studied**

Primary Sclerosing Cholangitis

**ICD-10 code**

K83.0

**ICD-10 code description**

Cholangitis

## Primary outcomes

**1**

**Description**
Alkaline phosphatase changes
**Timepoint**
Before the start of study and one month after the end of taking probiotics and placebo
**Method of measurement**
Alkaline phosphatase test

## Secondary outcomes

**1**

**Description**
Total bilirubin changes
**Timepoint**
Before the start of the study and one month after the end of taking probiotics and placebo
**Method of measurement**
Total bilirubin test

**2**

**Description**
Primary sclerosing cholangitis risk score changes, based on Mayo clinic
**Timepoint**
Before the start of the study and one month after the end of taking probiotics and placebo
**Method of measurement**
Primary sclerosing cholangitis risk score changes, based on Mayo clinic: A decision-making model for primary sclerosing cholangitis based on five variables: 1-Age in years 2-Total bilirubin in mg/dL 3-Serum albumin in g/dL 4-AST in IU/L 5-Variceal bleeding

## Intervention groups

**1**

**Description**
Intervention group: probiotic containing Lactobacillus rhamnosus, Bifidobacterium lactis, Lactobacillus casei Bifidobacterium bruh, Lactobacillus acidophilus, Bifidobacterium longum, Lactobacillus plantarum, Bifidobacterium bifidum and Streptococcus thermophilus Famie Lact brand (Zist takhmir Company, Tehran, Iran) is given two capsules daily for three months
**Category**
Prevention

**2**

**Description**
Control group: The capsules containing 100 mg of carboxymethylcellulose are used as a placebo, which in appearance, taste, and packaging box is similar to Femme Lactate, which is prepared by Zisttakhmir Co. Two capsules are given to the control group daily for three months. Patients take their medications routinely during the study.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Motahhari Clinic
**Full name of responsible person**
Fardad Ejtehadi
**Street address**
Shahid Motahari Specialized and Sub-Specialized Clinic, Namazi Square, Shiraz, Iran
**City**
Shiraz
**Province**
Fars
**Postal code**
71348714737
**Phone**
+98 71 3612 1000
**Email**
edjtehadif@sums.ac.ir
**Web page address**
https://motahari.sums.ac.ir/page-EmamRezaClinic/fa/52/form/pId2725

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Mahtab Memarpour
**Street address**
Seventh floor, Vice Chancellor for Research and Technology, the central building of Shiraz University of Medical Sciences, Zand St. Shiraz, Iran
**City**
Shiraz
**Province**
Fars
**Postal code**
7134814336
**Phone**
+98 71 3212 2430
**Email**
vcrdep@sums.ac.ir
**Web page address**
https://research.sums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Fardad Ejtehadi
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Internal medicine group office, Namazi hospital, Namazi Square, Zand St. Shiraz, Iran
**City**
Shiraz
**Province**
Fars
**Postal code**
7193613311
**Phone**
+98 21 3647 4316
**Email**
edjtehadif@sums.ac.ir
**Web page address**
https://med.sums.ac.ir/page-RightinternalMain/fa/311/form/pId52553

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Fardad Ejtehadi
**Position**
Associate professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
**Street address**
Internal medicine group office, Namazi hospital, Namazi Square, Zand St. Shiraz, Iran
**City**
Shiraz
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7193613311
**Phone**
+98 21 3647 4316
**Email**
edjtehadif@sums.ac.ir
**Web page address**
https://med.sums.ac.ir/page-RightinternalMain/fa/311/form/pId52553

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Nasrin Motazedian
**Position**
Assistant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Public Health/Community Medicine
**Street address**
7th floor, Transplant Research Center,Mohammad Rasool Allah Reserch Tower,Khalili Ave., Shiraz.
**City**
Shiraz
**Province**
Fars
**Postal code**
7193635899
**Phone**
0098716281529
**Email**
motazediann@yahoo.com
**Web page address**
https://strc.sums.ac.ir/

## 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 more information.
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable