Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 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
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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
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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
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Person responsible for updating data

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Email
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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