

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of Probiotics on elastographic findings of patients with nonalcoholic fatty liver disease

#### Protocol summary

##### Study aim

Effect of Probiotics on elastographic findings of patients with nonalcoholic fatty liver diseases

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 70 patients. Patients were randomly divided 2 group by block randomization.

##### Settings and conduct

Participants will be selected from patients with non-alcoholic fatty liver disease referred to the gastrointestinal clinics of Imam Reza Hospital. General information of patients will be extracted using a questionnaire. All patients will also undergo elastography. first group will be given the drug Rifaximin 550 mg twice a day for a week in addition to their usual treatments. After a week, they will receive probiotic capsules twice a day for 6 months. The control group will also take a placebo drug in addition to Will receive their usual. After completing 6 months of treatment, patients will undergo elastography again and the degree of stasis and liver fibrosis will be determined based on LSM and CAP criteria. Pre- and post-intervention findings will be compared.

##### Participants/Inclusion and exclusion criteria

inclusive criteria; Age 18 to 59 years; No history of alcohol; Do not take drugs with liver toxicity exclusive criteria ;liver disease with specific etiologies such as viral hepatitis; Cirrhosis;Pregnancy and lactation; Use nutritional supplements; antibiotic use

##### Intervention groups

case group studied after one week of probiotic capsules containing Lactobacillus rhamnosus, Bifidobacterium lactis, Lactobacillus casei, Bifidobacterium breve, Lactobacillus acidophilus, Bifidobacterium langum, Lactobacillus m. As a probiotic, they will receive 2 times a day for 6 months. And the control group will receive starch capsules with this pattern

##### Main outcome variables

Determination of the effect of probiotics on hepatic steatosis and fibrosis in patients with non-alcoholic fatty liver disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220104053626N1**

Registration date: **2022-01-11, 1400/10/21**

Registration timing: **retrospective**

Last update: **2022-01-11, 1400/10/21**

Update count: **0**

##### Registration date

2022-01-11, 1400/10/21

##### Registrant information

##### Name

Masood Dinevari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

dinvarim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-05-20, 1400/02/30

##### Actual recruitment start date

2021-04-30, 1400/02/10

##### Actual recruitment end date

2021-09-21, 1400/06/30  
**Trial completion date**  
2022-04-21, 1401/02/01

**Scientific title**  
Effect of Probiotics on elastographic findings of patients with nonalcoholic fatty liver disease

**Public title**  
The effect of probiotics on non-alcoholic fatty liver

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Age 18 to 59 years Willingness to participate in the study  
No history of alcohol consumption Do not take drugs with liver toxicity

**Exclusion criteria:**  
Having liver disease with specific etiologies such as viral hepatitis Cirrhosis of the liver alcohol consumption  
Pregnancy and lactation Take other nutritional supplements Recent 3 months of antibiotic use

**Age**  
From **18 years** old to **59 years** old

**Gender**  
Both

**Phase**  
1-2

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**  
Target sample size: **70**  
Actual sample size reached: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
From the patients who volunteered to participate in the study, 70 persons will be selected by simple random sampling. Randomization method: Randomization unit block: Individual Randomization layers: In each block, people will be matched based on age and gender. Random Allocation software: Random Allocation software How to create a random sequence: Using Random Allocation software Hide: The random sequence created is kept in a safe place and is done by an independent person who is not involved in the experiment during the study. Random allocation of hidden individuals, patients and researchers will not be aware of it.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
This study is a double-blind study in which the researcher of this study and the patients participating in the study will be unaware of the type of supplement received. Supplements will be provided to patients by another person who has no role in completing the questionnaire and performing blood tests. Patients will also be informed of the existence of two types of supplements (probiotics and placebo) when obtaining consent, but will

be unaware of which study groups they will be included in. Placebo capsules are similar in appearance, color, and size to probiotic capsules.

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**  
**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Tabriz University of Medical Sciences  
**Street address**  
Golgasht Ave., emamreza hospital., Tabriz  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5163996889

**Approval date**  
2021-04-12, 1400/01/23  
**Ethics committee reference number**  
IR.TBZMED.REC.1400.072

**Health conditions studied**

**1**  
**Description of health condition studied**  
Patients with non-alcoholic fatty liver disease diagnosed with ultrasound findings  
**ICD-10 code**  
K76.0  
**ICD-10 code description**  
Fatty (change of) liver, not elsewhere classified

**Primary outcomes**

**1**  
**Description**  
Determination of the effect of probiotics on hepatic steatosis in patients with non-alcoholic fatty liver disease in comparison with the control group

**Timepoint**  
After completing 6 months of treatment, patients will undergo elastography again and the degree of stasis will be determined based on LSM and CAP criteria. Pre- and post-intervention findings will be compared.  
**Method of measurement**  
After treatment, patients will undergo elastography again and the degree of stasis will be determined based on

LSM and CAP criteria. Pre- and post-intervention findings will be compared.

## 2

### **Description**

Determination of the effect of probiotics on hepatic fibrosis in patients with non-alcoholic fatty liver disease in comparison with the control group

### **Timepoint**

After completing 6 months of treatment, patients undergo elastography again and the degree of their liver fibrosis will be determined based on LSM and CAP criteria. The findings before and after the intervention will be compared.

### **Method of measurement**

After completing the treatment, the patients will undergo elastography again and their degree of liver fibrosis will be determined according to LSM and CAP criteria. The findings before and after the intervention will be compared.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In addition to their usual medications, Rifaximin 550 mg tablets will be given twice a day for a week after one week of probiotics containing a combination of Lactobacillus rhamnosus, Bifidobacterium lactis, Lactobacillus casei, Bifidobacterium brucei, Lactobacillus acidophilus, Bifidobacterium bifidum, Streptococcus thermophilus each will be in the amount (10 to the power of 9 CFU), as a probiotic will receive 2 times a day for 6 months Group

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: In addition to their usual medications, Rifaximin 550 mg tablets will be given twice a day for a week. After one week, they will receive the starch capsule as a medicine twice a day for 6 months.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza hospital

##### **Full name of responsible person**

Maryam Khalili

#### **Street address**

Golgasht Ave., Emam Reza hospital

#### **City**

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#### **Phone**

+98 41 3337 2084

#### **Email**

Maryam.khalili1305@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Masoud Faghieh Dinevari

##### **Street address**

Golgasht Ave., Emam Reza hospital

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##### **Email**

masood.dinevari@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Masoud Dinevari

##### **Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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Internal medicine department,Emam reza hospital,golgasht avenue,Daneshgah street

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

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

asistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Phone**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

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

**Data Dictionary**

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

**Title and more details about the data/document**

Only the results of the main outcome will be published in the form of an article

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

After the article is published, everyone will have access to the results

**Under which criteria data/document could be used**

After the article is published, everyone will have access to the results

**From where data/document is obtainable**

After the article is published, everyone will have access to the results

**What processes are involved for a request to access data/document**

After the article is published, everyone will have access to the results

**Comments**