

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 brove, 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)

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+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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Masoud Faghieh Dinevari

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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

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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Latest degree

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

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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