Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 diseas

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

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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 bruce, 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
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Full name of responsible person
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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
Masood Dinevari
Position
Assisstant professor

Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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