Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Effect of daily consumption of probiotic yogurt on liver enzymes steatosis and fibrosis in patients with nonalcoholic fatty liver disease

Protocol summary

Study aim
If appropriate, it is recommended to use probiotic yogurt in the diet of patients with non-alcoholic fatty liver

Design
A clinical trial with a control group, parallel group, randomized groups, on 68patients. lottery container was used for randomization.

Settings and conduct
A controlled clinical trial will be performed at the Gastroenterology Clinic. Before the intervention, anthropometric indices, blood pressure, liver enzymes, glycemic index, insulin resistance, hepatic steatosis, liver fibrosis and lipid profile will be evaluated in all subjects. Individuals will be randomly divided into intervention and non-intervention groups. Intervention: 300 g daily probiotic yogurt for 12 weeks, control: 300 g normal yogurt daily for 12 weeks. The yogurts have the same color, shape, taste and smell are used so that the researcher and the patient are not aware of its type and only our distributor is aware of its type.

Participants/Inclusion and exclusion criteria
1. Patients with non-alcoholic fatty liver disease, 2. Aged 18-65 years, 3. Body mass index between 25-35 kg/m2. 4. Patients have a fixed plan for medication use during the last 3 months.

Intervention groups
Intervention: daily 300g probiotic yogurt for 12 weeks, control: 300g normal yogurt for 8 weeks

Main outcome variables
Steatosis, fibrosis and liver enzymes including ALT, AST and GGT.

General information

Reason for update
Recruitment start date delayed due to Covid-19 pandemic and changed to December 2021.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210201050210N1**
Registration date: **2021-04-19, 1400/01/30**
Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**
Update count: **1**

Registration date
2021-04-19, 1400/01/30

Registrant information

Name
Sara Ebrahimi-Mousavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3761 3287

Email address
s-ebrahimim@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-06, 1400/09/15

Expected recruitment end date
2022-01-05, 1400/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of daily consumption of probiotic yogurt on liver enzymes steatosis and fibrosis in patients with nonalcoholic fatty liver disease

Public title

Effect of daily consumption of probiotic yogurt in patients with non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-alcoholic fatty liver disease was approved by a gastroenterologist using fibroscan examination Individuals aged 20 to 60 years Patients have a fixed plan for medication use during the last 3 months Body mass index between 25 to 35 kg/m 2

Exclusion criteria:

Smokers History of alcohol consumption Adherence to a special diet in the last 3 months Pregnant or lactating women or those planning to get pregnant in the next three months Menopausal women Individuals with pathologic conditions affecting the liver, including acute and chronic hepatitis, viral hepatitis, liver transplantation, autonomic hepatitis, hemochromatosis, primary biliary cirrhosis, Wilson's disease, antitrypsin deficiency and thyroid disease People with lactose intolerance People taking antibiotics patients taking medications affecting serum lipids Individuals taking multivitamin-minerals during the previous month Patients who have used any type of probiotic product in the last two months

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be classified based on age(20-40/40-60), gender (male/female) and BMI (25-30/30-35) into different blocks. To do randomization, an identification code will be given to each participant, and then the codes of each two participants with the same age, gender and BMI will be poured into the lottery container. Random allocation will be done by a person who is unaware of the study. The first code will be assigned to the intervention group, the second code to the control group and so other participants will be randomly assigned to the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape, appearance, packaging, color and smell of both probiotic and non-probiotic yogurts will be quite similar. In addition, the person who provides yogurts to patients is aware of the type of yogurt, but the researcher and the patient are not aware of it.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

First Floor, Faculty of Medicine, Building No. 1, North Door of the University, POURSINA St, GHODS St, ENGHELAB St

City

Tehran

Province

Tehran

Postal code

14155-6117

Approval date

2021-01-20, 1399/11/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.1006

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Hepatic steatosis

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Fibro-scan

2

Description

Hepatic fibrosis

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement
Fibro-scan

3

Description
Liver enzyme (ALT, AST and GGT)
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Blood sample

Secondary outcomes

1

Description
Lipid profile (TG, Total cholesterol, LDL-c and LDH-c)
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Blood sample

2

Description
Glycemic index (FBS, FBI, HOMA-IR and QUICKI)
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Blood sample

3

Description
Weight
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Scales

4

Description
Waist circumference
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Tape meter

5

Description
Body mass index (BMI)
Timepoint
Beginning the intervention and 12 weeks later at the end of the intervention
Method of measurement
Formula (weight (kilograms) divided by the squared height (meters))

Intervention groups

1

Description
Intervention group: They will receive 300g of probiotic yogurt enriched with Bifidobacterium lactis and Lactobacillus acidophilus strains daily for 12 weeks. Microbiological analyzes showed that the average colony content of both strains is 10 ^ 6 CFU / g.
Category
Rehabilitation

2

Description
Control group: Control group: 300g will receive conventional yogurt for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Seyyed Moayed Alaviyan's clinic
Full name of responsible person
Sara Ebrahimi-Mousavi
Street address
No. 178, Corner of Shadab Crossroads, Above Taleghani, Sepahbod Gharani St., Ferdowsi Square
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Tehran
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Postal code
1417935840
Phone
+98 21 8890 7154
Email
alavian@thc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Sahraeiyan
Street address
Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Ghods Street, Keshavarz Blvd.
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1417935840
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vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
50

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
Tehran University of Medical Sciences
Full name of responsible person
Sara Ebrahimi-Mousavi
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
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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)
Undecided - It is not yet known if there will be 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