

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Effects of Probiotic on IL6 and TNF-a levels on patients with nonalcoholic fatty liver disease

Protocol summary

Study aim

Effects of Probiotic on IL6 and TNF-a levels on patients with nonalcoholic fatty liver disease

Design

This study is a randomized, double-blind clinical trial with parallel groups and a control group that will be performed with the participation of 80 patients with fatty liver; Patients will be divided into intervention and control groups by block randomization

Settings and conduct

This clinical trial study will be performed with the participation of 80 patients with fatty liver disease referred to gastrointestinal clinics in Imam Reza Hospital (Tabriz Medical Sciences). ,IL6 and TNF-a level will be checked in initiation of study in all patients.first group will recieve probiotic capsules for 3 month.after completing 3 month ,IL6 and TNF-a level will be checked again and results will be compared pre and post intervention.researchers and patient and data analyzer will be blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: Age at 18-75 year,no history of alcohol consumption,Grade 2 in terms of fatty liver grading and willingness to participate in the study, and exclusion criteria also include: taking drugs with liver toxicity, history of antibiotic use in the last 3 months and liver disease with known etiology,such as viral hepatitis,Cirrhosis,pregnancy and lactation

Intervention groups

This study will be a randomized, double -blind clinical trial with parallel groups; 80 people will be randomly divided into two groups. Patients in the intervention group will take probiotic pills for three months and after three months, their IL6 and TNF levels will be measured; The control group will receive placebo.

Main outcome variables

Interleukin 6 and TNF-a secretion level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220104053626N3**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

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

2022-03-16, 1400/12/25

Expected recruitment end date

2022-06-15, 1401/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Probiotic on IL6 and TNF-a levels on patients with nonalcoholic fatty liver disease	
Public title	The effect of probiotics in patients with non-alcoholic fatty liver disease
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Grade two in terms of fatty liver grading Willingness to participate in the study no alcohol consumption age 18-75
Exclusion criteria:	Take drugs with liver toxicity Recent 3 months of antibiotic use Hepatitis B and C cirrhosis pregnancy and lactation
Age	From 18 years old to 75 years old
Gender	Both
Phase	2-3
Groups that have been masked	• Participant • Investigator • Data analyser
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Randomized
Randomization description	From the patients who volunteered to participate in the study, 80 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	2022-01-19, 1400/10/29
Ethics committee reference number	IR.TBZMED.REC.1400.1095
Health conditions studied	
1	
Description of health condition studied	Fatty Liver
ICD-10 code	K76.0
ICD-10 code description	Fatty (change of) liver, not elsewhere classified
Primary outcomes	
1	
Description	Interleukin 6
Timepoint	Before the intervention and after the intervention
Method of measurement	Biochemical tests-ELISA
2	
Description	TNF-a level
Timepoint	before and after intervention
Method of measurement	ELISA
Secondary outcomes	empty

Intervention groups

1

Description

Intervention group: Patients will be included in this group after random allocation. All patients will receive routine treatment and, in addition to routine medications, will take probiotic pills twice daily for three months. Interleukin 6 levels will be measured before the intervention and after the intervention.

Category

Treatment - Other

2

Description

Control group: Patients will be included in this group after random allocation. All patients will receive routine treatment and, in addition to routine medications, will receive two placebo tablets daily for three months. Interleukin 6 levels will be measured before the intervention and after the intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam reza hospital

Full name of responsible person

Tahereh Vaezi

Street address

Emam reza hospital, Golgast st,Tabriz.

City

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Province

East Azarbaijan

Postal code

566614766

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+98 41 3334 4918

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farzanehjafarzadeh998@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

Golgasht Ave., Emam Reza hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5164886994

Phone

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Email

Shahabi_p@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

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

Tabriz University of Medical Sciences

Full name of responsible person

Masood Dinevari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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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)**

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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable