Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The effects of probiotic, prebiotic and concomitant supplementation of probiotic, Prebiotic on the oxidative stress, inflammatory and insulin resistance indices, lipid profile and liver function in non-alcoholic fatty liver. patients.

Protocol summary

Summary

1) Objectives: Compared dietary supplementation with probiotic, prebiotic and Concomitant supplementation of probiotic and prebiotic on the oxidative stress, inflammatory and insulin resistance indices, lipid profile and liver function in NAFLD patients; 2) Design: Randomized double-blind placebo controlled trial; 3) Setting and conduct: Subjects will randomly divide into 4 groups including 22 subjects: Group1 will receive probiotic and placebo of prebiotic; Group 2 will receive prebiotic and placebo of probiotic; Group 3 will receive probiotic and prebiotic; Group 4 will receive placebo of probiotic and placebo of prebiotic. For each patient anthropometric measurements (height, weight and BMI) will be assessed and general characteristics and 24-h food record questionnaire in order to assessment of food intake for 3 days a week at the baseline and end of the study will be filled; 4) Participants including inclusion criteria: NAFLD patients with age between 20-60 (both of gender) years agreed to participate the study. Exclusion criteria: Pregnancy and lactation; viral hepatitis B and C; cardiovascular; thyroid; renal; autoimmune and inflammatory disorders; hemochromatosis; Wilson disease; usage of alcohol and supplements of A, E, C, 5). Intervention: Group1 will receive 1 gr of probiotic (107 Bifidobacterium longum and Lactobacillus acidophilus) and 5 gr of prebiotic placebo (multodextrose) twice daily; Group 2 will receive 5 gr of prebiotic (inulin HP) and 1 gr of probiotic placebo (powder milk free fat and sugar) twice daily; Group 3 will receive 1 gr of probiotic (107 Bifidobacterium longum and Lactobacillus acidophilus) and 5 gr of prebiotic (inulin HP) twice daily and group 4 will receive 1 gr of probiotic placebo (powder milk free fat and sugar) and 5 gr of prebiotic placebo (multodextrose) twice daily; All of patients will follow up for 3 months. 6) Main outcome measures variables: Obesity indices (body mass indices, west to hip ratio) and the experiments of oxidative stress (MDA، TAC), inflammatory testes (hs-CRP ،TNF-α IL-6), insulin resistance indices (FBS, Insulin), lipid profile (TC، TG، LDL ، HDL), ultrasound of liver and liver function testes (ALP، AST، BIL ، ALB، γGT،ALT) before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301223140N6**
Registration date: **2014-01-16, 1392/10/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-01-16, 1392/10/26

Registrant information

Name

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Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Nutrition research center university medicinal science Tabriz

Expected recruitment start date
2013-12-22, 1392/10/01
Expected recruitment end date
2014-07-21, 1393/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of probiotic, prebiotic and concomitant supplementation of probiotic, Prebiotic on the oxidative stress, inflammatory and insulin resistance indices, lipid profile and liver function in non-alcoholic fatty liver. patients.

Public title
The effects of probiotic and prebiotic in Nonalcoholic fatty liver disease.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: non-alcoholic fatty liver patients with age between 20-60 (both of gender) years agreed to participate the study. Exclusion criteria: Pregnancy and lactation; viral hepatitis B and C; cardiovascular; thyroid; renal; autoimmune and inflammatory disorders; hemochromatosis; Wilson disease; usage of alcohol and supplements of A,E,C.
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
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
Tabriz University of Medical Science ,Golgasht street, Tabriz.
City
Tabriz
Postal code
Approval date
2013-11-18, 1392/08/27
Ethics committee reference number
92128

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver
ICD-10 code
k76.0
ICD-10 code description
Other diseases of liver

Primary outcomes

1

Description
AST
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

2

Description
ALT
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

3

Description
γGT
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

4

Description
ALP
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

5

Description
ALB
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

6

Description
BIL
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

7

Description
TC
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

8

Description
TG
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

9

Description
LDL
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

10

Description
HDL
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

11

Description
hs-CRP
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

12

Description
TNF-α
Timepoint
Befor and after intervention
Method of measurement
Serum of blood,ELISA

13

Description
IL-6
Timepoint
Befor and after intervention
Method of measurement
Serum of blood,ELISA

14

Description
MDA
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

15

Description
TAC
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

16

Description
Insulin
Timepoint
Befor and after intervention
Method of measurement
Serum of blood,ELISA

17

Description
FBS
Timepoint
Befor and after intervention
Method of measurement
serum of blood, by outoanalyzer

18

Description
HOMA-IR
Timepoint
Befor and after intervention
Method of measurement
srrum insulin*FBS/405

Secondary outcomes

1

Description
Body mass index
Timepoint
Befor and after intervention
Method of measurement
W/H2

2

Description
WRT
Timepoint
Befor and after intervention
Method of measurement
waist to hip ratio

3

Description
Intake micro and macro nutrients
Timepoint
Befor and after intervention
Method of measurement
Three days weighing food questionnaires

Intervention groups

1

Description
Intervention groups: Group1 treated with 1 gr of probiotic capcul (107 Bifidobacterium longum and Lactobacillus acidophilus) and 5 gr of prebiotic plasebo (multodextrose) twice a day for 3 months. Group 2 treated with 5 gr of prebiotic (inulin HP) and 1 gr of placebo probiotic (powder milk free fat and suger) twice a day for 3 months. Group 3 treated with 1 gr of probiotic (107 Bifidobacterium longum and Lactobacillus acidophilus) and 5 gr of prebiotic (inulin HP) twice a day for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Group 4 treated with 1 gr of probiotic placebo (powder milk free fat and sugar) and 5 gr of prebiotic placebo (multodextrose) twice a day for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Azadi medicinal clinic
Full name of responsible person
Leila Javadi
Street address
Azadi medicinal clinic, Azadi street, Tabriz
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research-Tabriz University of Medical Science
Full name of responsible person
Mohammadreza Rashidi
Street address
Vice-chancellor for research-Tabriz University of Medical Science، Golgasht street، Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research-Tabriz University of Medical Science
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Nutrition Research Center of Univercity Medicinal Science Tabriz
Full name of responsible person
Alireza Ostadrahimi
Street address
Nutriton Research Center, Nutrition Faculty, AttareNeishabouri Avenue, Golgasht street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Nutrition Research Center of Univercity Medicinal Science Tabriz

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Nutrition Research Center, Tabriz University of Medical Sciences, Tabriz

Full name of responsible person

Leila Javadi

Position

PhD Student of Nutrition Research Center

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty