

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, waist 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, γ GT, 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

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

Country

Iran (Islamic Republic of)

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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 utooanalyzer

6

Description

BIL

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

7

Description

TC

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

8

Description

TG

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

9

Description

LDL

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

10

Description

HDL

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

11

Description

hs-CRP

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

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 utooanalyzer

15

Description

TAC

Timepoint

Befor and after intervention

Method of measurement

serum of blood, by utooanalyzer

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 utooanalyzer

18

Description

HOMA-IR

Timepoint

Befor and after intervention

Method of measurement

srrum insulin*FBS/405

Secondary outcomes

1

Description

Body mass index

Timepoint

Before and after intervention

Method of measurement

W/H2

2

Description

WRT

Timepoint

Before and after intervention

Method of measurement

waist to hip ratio

3

Description

Intake micro and macro nutrients

Timepoint

Before and after intervention

Method of measurement

Three days weighing food questionnaires

Intervention groups

1

Description

Intervention groups: Group1 treated with 1 gr of probiotic capsule (107 Bifidobacterium longum and Lactobacillus acidophilus) and 5 gr of prebiotic placebo (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 sugar) 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 University Medicinal Science Tabriz

Full name of responsible person

Alireza Ostadrahimi

Street address

Nutrition 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 University 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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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