

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Assessing the Effects of probiotic and prebiotic supplementation on serum hepatic enzymes, Insulin resistance, hs-CRP, Lipid profile, leptin and Adiponectin in patients with NAFLD

Protocol summary

Summary

Objective: Assessing the effect of probiotic and prebiotic supplementation on liver enzymes and inflammatory markers (hsCRP), leptin, adiponectin, insulin resistance, lipid profile in patients with NAFLD. 2. Double blind randomized clinical trial, a placebo-controlled, single-center. 3. 105 patients with Non-alcoholic fatty liver disease that will be referred to Afzalipour hospital in Kerman and having inclusion criteria are selected. They were divided into 3 groups randomly: intervention 1 (probiotic supplementation and prebiotic placebo) intervention 2 (prebiotic supplementation and probiotic placebo) and control group (probiotic and prebiotic placebo) And the 3-month intervention done. Before and after the intervention, 10 ml of fasting blood was taken from them. For Dietary assessment of patients and control potential confounding factors of diet, 3-day dietary recall questionnaire and physical activity questionnaire (IPAQ) is completed. Patient anthropometric data including weight, height, waist circumference, hip circumference, body fat and blood pressure will be measured. 4. Main inclusion criteria: Patients with Non-alcoholic fatty liver disease, body mass index above 25 and below 40, the absence of other diseases, not pregnancy and lactation, aged 20 -60, Lack of drug use. Main Exclusion criteria: Pregnancy, the use of antibiotics over 1 week, Any changes in diet and physical activity. 5. Outcome: Liver enzymes (GGT, ALP, ALT, AST), lipid profile (LDL, HDL, TG, Chol), Adipocytokines (leptin and adiponectin), Insulin resistance (FBS, insulin, HOMA-IR, QUICKI), inflammatory marker hs-CRP, anthropometric measures (percent body fat, waist circumference, weight) and blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410052394N13**
Registration date: **2014-12-14, 1393/09/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-14, 1393/09/23

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing the Effects of probiotic and prebiotic supplementation on serum hepatic enzymes, Insulin resistance, hs-CRP, Lipid profile, leptin and Adiponectin in patients with NAFLD

Public title

The effects of probiotic and prebiotic supplementation on Non Alcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate and signed the consent; Elevated serum levels of liver enzymes(ALT greater than 1.5 times normal); More than one degree of steatosis on ultrasonography in patients; No alcohol abuse (consuming more than 10 grams for women and 20 grams for men) and opium abuse; Body Mass Index equal to or greater than 25 Kg/m² and equal to or less than 40 Kg/m²; The absence of other acute and chronic diseases and disorders of the liver (hepatitis B, C, ...), cirrhosis, celiac disease, diabetes, hypertension, cardiovascular disease, kidney disease, lung disease; No pregnancy and lactation; Not taking metformin, vitamin E, orso de Oxy-colic acid and weight-loss drugs, hepatotoxic , antibiotics, corticosteroids, NSAIDs and other medications; no history of weight loss surgery in the past year; Failure to lose weight in 3 months; nonsmoking; aged 20-60 years; without the use of supplemental multivitamins, minerals and omega-3 (nutritional supplements); not using the contraceptive pill. Exclusion criteria: Taking antibiotics for over a week during the study period; Personal desire to withdraw from the study; Not consume more than 10% of the capsules at any follow up; Any changes in recommended diet and daily physical activity; being pregnant during the intervention.

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: **105**

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 Iran university of medical science

Street address

Department of Nutrition, School of public Health, Iran University of Medical Sciences, Shahid Hemmet Highway, Tehran, Iran

City

Tehran

Postal code**Approval date**

2014-11-12, 1393/08/21

Ethics committee reference number

93-03-27-24996

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**

ALT

Timepoint

At baseline, after 12 weeks

Method of measurement

photometric assay

2**Description**

AST

Timepoint

At baseline, after 12 weeks

Method of measurement

photometric assay

3**Description**

γGT

Timepoint

At baseline, after 12 weeks

Method of measurement

Enzymatic colorimetric assay

4

Description

ALP

Timepoint

At baseline, after 12 weeks

Method of measurement

photometric assay

5

Description

hs-CRP

Timepoint

At baseline, after 12 weeks

Method of measurement

ELISA

6

Description

Leptin

Timepoint

At baseline, after 12 weeks

Method of measurement

ELISA

7

Description

Adiponectin

Timepoint

At baseline, after 12 weeks

Method of measurement

ELISA

8

Description

Insulin

Timepoint

At baseline, after 12 weeks

Method of measurement

ELISA

9

Description

HOMA-IR

Timepoint

At baseline, after 12 weeks

Method of measurement

Serum insulin*FBS/405

10

Description

QUICKI

Timepoint

At baseline, after 12 weeks

Method of measurement

Calculation

11

Description

Fasting Glucose

Timepoint

At baseline, after 12 weeks

Method of measurement

GOD/POD

12

Description

TG

Timepoint

At baseline, after 12 weeks

Method of measurement

Enzymatic colorimetric assay

13

Description

Cholestrol

Timepoint

At baseline, after 12 weeks

Method of measurement

Enzymatic colorimetric assay

14

Description

LDL

Timepoint

At baseline, after 12 weeks

Method of measurement

Calculation

15

Description

Blood pressure

Timepoint

At baseline, after 12 weeks

Method of measurement

sphygmomanometer

Secondary outcomes

1

Description

Body mass index

Timepoint

At baseline, after 12 weeks

Method of measurement

calculation

2

Description

WHR

Timepoint

At baseline, after 12 weeks

Method of measurement

calculation

3

Description

percentage body fat

Timepoint

At baseline, after 12 weeks

Method of measurement

BIA

Intervention groups

1

Description

Intervention group 1: Patients in the group receiving the probiotic supplement, 1 capsule contains a combination of probiotics comprising of five bacterial species (5 billion active cell, containing Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus acidophilus, Bifidobacterium longum, Bifidobacterium breve) with placebo prebiotics in the 2 cups 7/5 g (maltodextrin) daily receive. Intervention group 2: Patients in the group receiving the prebiotic supplement, Oral powder of oligo fructose (7.5 g 2 cup) with probiotic placebo (starch) in 1 capsule per day , that are similar in appearance probiotic supplement, receive.

Category

Treatment - Drugs

2

Description

In the placebo group, 2 cups of 7.5 g oral powder maltodextrin as probiotic supplement placebo and one capsule containing starch as prebiotic supplement placebo receive. Used placebo is similar to their respective supplements apparently.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital, Kerman University of Medical Sciences

Full name of responsible person

Dr. Mohammad Javad Zahedi

Street address

Afzalipour hospital, near Shahid Bahonar University, Emam highway, Kerman, Iran

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javad Moosavi

Street address

7th Floor, Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave., Tehran, Iran.

City

Tehran

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, Iran University of Medical Sciences

Proportion provided by this source

100

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

Department of Nutrition, School of public Health, Iran University of Medical Sciences.

Full name of responsible person

Vahideh Behrouz

Position

The MSc student of nutrition science

Other areas of specialty/work

Street address

Department of Nutrition, Faculty of Health, Iran University of Medical Sciences, near milad Hospital, Shahid Hemmat Highway, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8862 2806

Fax

Email

vahideh.behrouz@gmail.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Department of Nutrition, School of public Health, Iran
University of Medical Sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

MD, PhD /Assistant Professor

Other areas of specialty/work

Street address

Department of Nutrition, Faculty of Health, Iran
University of Medical Sciences, near milad Hospital,
Shahid Hemmat Highway, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8862 2806

Fax

Email

sh_jazayeri@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Nutrition, School of public Health, Iran
University of Medical Sciences

Full name of responsible person

Vahideh Behrouz

Position

The MSc student of Nutrition science

Other areas of specialty/work

Street address

Faculty of Health, Iran University of Medical Sciences,
near milad Hospital, Shahid Hemmat Highway,
Tehran, Iran.

City

Tehran

Postal code

Phone

00

Fax

Email

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