Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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 reffered to Afzalipour hospital in Kerman and having inclusion criteria are selected.They were divided into 3 groups randomely: 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), Adipocitokines (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)

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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 recieve. 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
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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

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The MSc student of nutrition science
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Person responsible for updating data

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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