Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Effects of Symbiotic on inflammatory markers, liver function, lipid profile, sonographic findings and body composition in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Protocol summary

Summary

This study is a double blind randomized clinical trial. The goal of our study is to determine the effects of symbiotic on inflammatory markers, liver function, lipid profile, sonographic findings and body composition in patients with Non-Alcoholic Fatty Liver Disease (NAFLD). A sample of 80 NAFLD patients aged 18-60 years will be enrolled in the study. The exclusion criteria are other chronic liver diseases, Inflammatory Bowel Diseases, Diabetes Mellitus, Cancer, consumption of some drugs or supplements. The patients by Block Randomization for age, sex, Body Mass Index (BMI) and Livergol or Metformin consumption, will be randomized to one of the two treatment and control groups. Patients in the first group will be treated with one tablet of synbiotic supplement contain 500 mg of seven Probiotic bacteria species and Fructooligosaccharides per day and control group will be treated with one placebo tablet per day. Physical activity and dietary recommendation will be given to both groups. The intervention will continue for 8 weeks. Liver Ultrasonography, routine liver tests, lipid profile, inflammatory markers and body composition will be evaluated on baseline and again after the intervention. Dietary intake and physical activity status will be determined by dietary record and physical activity record on the end of weeks 2, 4 and 6.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122811763N15**
Registration date: **2014-01-02, 1392/10/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-01-02, 1392/10/12

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-01-10, 1392/10/20

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Symbiotic on inflammatory markers, liver function, lipid profile, sonographic findings and body composition in Patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Public title

Effect of Symbiotic on Non-Alcoholic Fatty Liver Disease

(NAFLD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:aged 18-60 years; confirmation of NAFLD with Ultrasonography and increased levels of Ast and Alt; desire to participate in the study. Exclusion criteria: organ transplantation; presence of pregnancy and lactation; suffering from Wilson disease; chronic liver diseases unless NAFLD; Diabetes Mellitus; Cancer; antibiotics therapy; Receiving Oral Contraceptive Pill (OCP); drugs such as corticosteroids, Amiodarone, Tamoxifen, Cyclins, Perhexiline, Methotrexate and Hydralazine; Receiving of vitamin-mineral and omega-3 Supplements during the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

This study will be a double blind clinical trial. The researcher and the patients will not know that each patient will be in which group, treatment or control. The supplements and placebo tablets will be coded as A and B in similar packets by a person that will be unaware from goals of the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hearjarib St. Azadi Square

City

Isfahan

Postal code

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

392326

Health conditions studied

1

Description of health condition studied

NAFLD

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver

Primary outcomes

1

Description

Fatty liver grade

Timepoint

before and after the intervention

Method of measurement

Ultrasonography

2

Description

Alt_Ast

Timepoint

before and after the intervention

Method of measurement

by laboratory analysis (blood tests)

3

Description

lipid profiles

Timepoint

before and after the intervention

Method of measurement

by laboratory analysis (enzymatic)

4

Description

inflammatory markers

Timepoint

before and after the intervention

Method of measurement

Enzyme-Linked Immunosorbent Assay (ELISA)

5

Description

body composition

Timepoint

before and after the intervention

Method of measurement

Bioelectrical Impedance Assessment

Secondary outcomes

empty

Intervention groups

1

Description
Daily oral consumption of Symbiotic supplement produced by Zist takhmir company with Familact commercial name contain 500 mg of seven Probiotic bacteria species and Fructooligosaccharides with below composition for two months: Lactobacillus Casei, Lactobacillus Acidopholus, Lactobacillus Rhamnosus, Lactobacillus Bulgaricus, Bifidobacterium Breve, Bifidobacterium Longum, Streptococcus Thermophiles and giving physical activity and dietary recommendation about NAFLD to patients at the baseline

Category
Treatment - Drugs

2

Description
Daily Oral consumption of one tablet /day of placebo contain starch for two months and dietary recommendation about NAFLD to patients at the baseline

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Endocrinology and Metabolism Research Center

Full name of responsible person
Atefe Asgharian

Street address
Department of Community Nutrition School of Nutrition and Food Sciences Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person
Peyman Adibi

Street address
Isfahan University of Medical Sciences, Hearjarib St. Azadi Square

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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, Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Atefe Asgharian

Position
MSc student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Gholamreza Asgari

Position
Ph.D of nutrition, Assistant Professor

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