

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

##### 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 Acidophilus, 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

#### City

Isfahan

### 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

#### Street address

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+98 31 1222 4458

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Asgharian.Atefe@yahoo.com;

Asgharian.Atefe@gmail.com; Asgharian@skums.ac.ir

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Gholamreza Asgari

#### Position

Ph.D of nutrition, Assistant Professor

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Atefe Asgharian  
**Position**  
MSc of Nutrition  
**Other areas of specialty/work**  
**Street address**  
Department of Community Nutrition School of  
Nutrition and Food Sciences Isfahan University of  
Medical Sciences, Hezar Jarib Street, Isfahan  
**City**

## 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*