

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effects of synbiotic supplement containing *Bacillus coagulans* and inulin on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

#### Protocol summary

##### Study aim

To investigate The efficacy of synbiotic supplement containing *Bacillus coagulans* and inulin on lipid profile, liver enzymes, inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

##### Design

Adult NAFLD (n=50) will be randomized to receive a synbiotic containing *Bacillus coagulans* or placebo for 12 weeks. Before and after the intervention blood samples will be collected. Blood samples will be used to measure lipid profile, G-glutamyltransferase (GGT), ALT, AST, TNF- $\alpha$ , C-reactive protein, Fasting blood glucose levels and Serum insulin concentrations. The steatosis and hepatic fibrosis in patients will be measured using liver fibroscan at the beginning and the end of the study. The physical activity of patients was measured by the metabolic equivalent of task (MET) questionnaire at the beginning and the end of the study.

##### Settings and conduct

National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Patients with Nonalcoholic Steatohepatitis in the absence of exclusion criteria

##### Intervention groups

synbiotic Placebo

##### Main outcome variables

Lipid profile liver enzymes (AST and ALT), inflammatory factors: hs- CRP ,TNF- $\alpha$  and NF- $\kappa$ B, Fasting blood glucose, insulin level, liver fibrosis/steatosis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100524004010N23**

Registration date: **2018-04-18, 1397/01/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-18, 1397/01/29**

Update count: **0**

##### Registration date

2018-04-18, 1397/01/29

##### Registrant information

###### Name

Azita Hekmatdoost

###### Name of organization / entity

Shahid Beheshti University of Medical Sciences,  
National Institute of Nutrition Research

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2293 0824

###### Email address

hekmat@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-04-21, 1397/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of synbiotic supplement containing *Bacillus coagulans* and inulin on lipid profile, liver enzymes,

inflammatory factors and hepatic fibrosis in patients with Nonalcoholic Steatohepatitis

### Public title

Investigate the effects of synbiotic supplement containing Bacillus coagulans and inulin in the treatment of non-alcoholic fatty liver

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Inclusion Criteria for the study: Age >18 years old; Fill out the form consent and approve it; Controlled Attenuation Parameter (CAP score)>263; Having a history of alcohol consumption less than 10 mg per day in women and less than 20 mg per day in men; Absence of other acute and chronic diseases and disorders of the liver (hepatitis B, C, etc.), biliary disease, known autoimmune diseases, cancer and inherited disorders affecting liver condition (storage disease of iron, and copper. ..); Absence of Hypertension, cardio - vascular diseases, lung disease and kidney disease, cirrhosis and celiac disease; Absence of pregnancy or lactation, athletes or hospitalization; Not consume medications such as metformin, vitamin E and Ursodeoxycholic Acid (UDCA); Not consume hepatotoxic drugs such as phenytoin, tamoxifen and lithium and corticosteroids and methotrexate; Not consume medications of antibiotics over a week during the study period or before entering it; No history of weight loss surgery in the past year the 3-month weight loss program; No history of hypothyroidism, Cushing's syndrome and diabetes , lack of gall bladder disease. Exclusion Criteria for the study: Food intolerance and unlikely side effects from taking supplements; pregnancy..

#### Exclusion criteria:

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Investigator

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients will be randomly assigned to receive synbiotic or placebo.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Randomly assigned to intervention and placebo groups

### Placebo

Used

### Assignment

Parallel

### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

National Nutrition and Food Technology Research Institute, Shahid Beheshti University of Medical Sci

##### Street address

West arghavan, Sanaat square, Farahzadi boulevard, Shahrake gharb

##### City

Tehran

##### Province

Tehran

##### Postal code

193954741

#### Approval date

2017-11-15, 1396/08/24

#### Ethics committee reference number

IR.SBMU.nnftri.Rec.1396.163

### Health conditions studied

#### 1

#### Description of health condition studied

non alcoholic fatty liver disease

#### ICD-10 code

Other spec

#### ICD-10 code description

K75.8

### Primary outcomes

#### 1

#### Description

LDL-C

#### Timepoint

Beginning and end of intervention

#### Method of measurement

enzymatic methods using kits

#### 2

#### Description

Total cholesterol

#### Timepoint

Beginning and end of intervention

#### Method of measurement

enzymatic methods using kits

#### 3

#### Description

HDL-C  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
enzymatic methods using kits

#### 4

**Description**  
TG  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
enzymatic methods using kits

#### 5

**Description**  
FBS  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
enzymatic methods using kits

#### 6

**Description**  
Serum insulin  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
Radioimmunoassay

#### 7

**Description**  
AST  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
enzymatic methods using kits

#### 8

**Description**  
ALT  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
enzymatic methods using kits

#### 9

**Description**  
HOMA  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
Calculation

#### 10

**Description**  
TNF- $\alpha$

**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
Elisa

#### 11

**Description**  
Steatosis  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
ultrasonography

#### 12

**Description**  
Fibrosis  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
fibroscan

### Secondary outcomes

#### 1

**Description**  
SFA  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
questionnaire gram per day

#### 2

**Description**  
MUFA  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
questionnaire gram per day

#### 3

**Description**  
PUFA  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
questionnaire gram per day

#### 4

**Description**  
Carbohydrate intake  
**Timepoint**  
Beginning and end of intervention  
**Method of measurement**  
questionnaire gram per day

## 5

### **Description**

Protein intake

### **Timepoint**

Beginning and end of intervention

### **Method of measurement**

questionnaire gram per day

## 6

### **Description**

Fat intake

### **Timepoint**

Beginning and end of intervention

### **Method of measurement**

questionnaire gram per day

## **Intervention groups**

### 1

#### **Description**

Intervention group: 2 synbiotic capsule containing Bacillus coagulans(0.1) g and inulin(0.9 g) per day for 3 months

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: 2 placebo capsule containing 1gram maltodextrin per day for 3 months

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Taleqani Hospital

##### **Full name of responsible person**

Amir Sadeghi

##### **Street address**

Arabi Ave, Daneshjoo Blvd, Velenjak

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985711151

##### **Phone**

+98 21 2243 2560

##### **Email**

taleghanihospital@sbmu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

##### **Street address**

West arghavan, Sanaat square, Farahzadi boulevard, Shahrake gharb

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

00

##### **Phone**

+98 21 23871

##### **Email**

A\_hekmat2000@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Shahid Beheshti University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Azita Hekmatdoost

##### **Position**

Associate professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Nutrition

##### **Street address**

West arghavan, Sanaat square, Farahzadi boulevard, Qods Town

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

00

##### **Phone**

+98 912 306 5084

**Email**

A\_hekmat2000@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azita Hekmatdoost

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

West arghavan, Sanaat square, Farahzadi boulevard,  
Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

11

**Phone**

+98 912 306 5084

**Email**

A\_hekmat2000@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

خدیجه ابهری

**Position**

Postdoctoral Fellowship

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Food safety and Health

**Street address**

West arghavan, Sanaat square, Farahzadi boulevard,  
Shahrake gharb

**City**

Tehran

**Province**

Tehran

**Postal code**

00

**Phone**

+98 917 303 2478

**Email**

m65abhari@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The patients information is private.

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available