Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Sep 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-α, 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-α and NF-κB, 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
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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 boulvard, 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
Begining and end of intervention

Method of measurement
enzymatic methods using kits

2

Description
Total cholestrol

Timepoint
Begining and end of intervention

Method of measurement
enzymatic methods using kits

3

Description

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

4

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

5

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

6

Description
Serum insulin
Timepoint
Begining and end of intervention
Method of measurement
Radioimmunoassay

7

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

8

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

9

Description
HOMA
Timepoint
Begining and end of intervention
Method of measurement
Calculation

10

Description
TNF-α
Timepoint
Begining and end of intervention
Method of measurement
Elisa

11

Description
Steatosis
Timepoint
Begining and end of intervention
Method of measurement
ultrasonography

12

Description
Fibrosis
Timepoint
Begining and end of intervention
Method of measurement
fibroscan

Secondary outcomes

1

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

2

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

3

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

4

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

5

Description
Protein intake
Timepoint
Begining and end of intervention
Method of measurement
questionnaire gram per day

6

Description
Fat intake
Timepoint
Begining 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
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Sponsors / Funding sources

1

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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
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
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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