Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of Spirulina supplementation on anthropometric index, blood glucose, lipid profile, liver enzymes and cardiometabolic risk factors in nonalcoholic fatty liver disease patients: A randomized double-blinded clinical trial

Protocol summary

Study aim
The effect of Spirulina supplementation on the anthropometric index, blood glucose, lipid profile, liver enzymes and cardiometabolic risk factors in nonalcoholic fatty liver disease patients: A randomized double-blinded clinical trial

Design
Randomized, double-blind, placebo-controlled

Settings and conduct
In this study, patients with non-alcoholic fatty liver referring to Taleqani Hospital, if they wish to participate in the study informed consent of them will be taken. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, inflammatory factors, and other serum biochemical parameters and kept in the freezer. Participants randomly using the divided randomly classified into two groups: supplement and placebo groups.

Participants/Inclusion and exclusion criteria
Age >18 years old, ALT> 40 and AST>38, Ultrasound report grade 1 or 2 or three of fatty liver, Having

Intervention groups
Patients group supplement will be received daily 3 grams of Spirulina for 12 weeks and Patients in the control group will be recived placebo daily 3 grams.

Main outcome variables
Low Density Lipoprotein Cholestrol (LDL-C), High Density Lipoprotein Cholestrol (HDL-C), Triglyceride(TG), Total Cholestrol, Fasting Blood Sugar(FBS), Insulin, Homeostatic Model Assessment for Insulin Resistance(HOMA-IR), Aspartate Aminotransferase(AST), Alanine Aminotransferase(ALT), GSH, hs-CRRP, total antioxidant capacity, Liver Steatosis, Age, Sex, Smoking, Weight, Height, Waist Circumference, Hip Circumference, Waist to Hip Ratio(WHR), Body Mass Index(BMI), Total energy intake, Total carbohydrate intake, Total fat intake, Total protein intake, Total fiber intake, Total SFA intake, Total MUFA intake, Total PUFA intake

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110510006431N5**
Registration date: **2022-09-14, 1401/06/23**
Registration timing: **prospective**

Last update: **2022-09-14, 1401/06/23**
Update count: **0**

Registration date
2022-09-14, 1401/06/23

Registrant information

Name
Mahdi Shadnoush

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2240 1423

Email address
shadnoush@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Spirulina supplementation on anthropometric index, blood glucose, lipid profile, liver enzymes and cardiometabolic risk factors in nonalcoholic fatty liver disease patients: A randomized double-blinded clinical trial

Public title

effect of Spirulina in nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥18 years old, AST > 38, ALT > 40, Steatohepatitis grade 1,2 or 3 according to Ultrasound report, Having a history of alcohol consumption of less than 10 gram per day in women and less than 20 gram per day in men, Absence of other acute and chronic diseases and liver disorders (hepatitis B, C, etc.), biliary disease, known autoimmune diseases, cancer and inherited disorders affecting liver condition (storage disease of iron, and copper. ..), Hypertension, cardiovascular diseases, lung disease and kidney disease, cirrhosis, and celiac disease, Absence of pregnancy or lactation, Athletes or hospitalization, No consumption medications such as metformin, vitamin E and Ursodeoxycholic Acid (UDCA), No consumption hepatotoxic drugs such as phenytoin, tamoxifen and lithium, and corticosteroids and methotrexate, No consumption medications or antibiotics over a week during the study period or before entering it, No history of weight loss surgery in during year during, weight loss program during past 3-month, No history of hypothyroidism, Cushing's syndrome, and diabetes, Lack of gall bladder disease

Exclusion criteria:

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are divided into 2 intervention groups: intervention (as Spirulina supplement group) and control group (as placebo group) (named groups A and B), to randomly assign patients to two groups of methods. Stratified blocked randomization is used. The division of branches is based on gender, so patients are first classified into two groups based on gender: male and female (as 2 to Strata). After specifying the quadruple blocks in different arrangements (AABB, ABAB, ABBA, etc.), the lottery method with placement is used to determine the treatment allocation list. It is also necessary to explain that in order to observe the concealment in the mentioned plan, the randomization operation is performed by a person other than the main researcher, and the codes specified in the packets in the package after randomization are provided to the researchers for random sampling and assignment. Placed in the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. A person other than the researcher who has no information about how to perform and the purpose of the study will use a list of random numbers to encode the Spirulina supplement and placebo and will be numbered according to the list so that the researcher does not know The type of supplements should be observed by each group. Participants will also have no information about the contents of the package.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

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Arabi Ave, Daneshjoo Blvd, Velenjak

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Postal code

1985717443

Approval date

2022-05-28, 1401/03/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.178

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver Disease
ICD-10 code
K75.8
ICD-10 code description
Other specified inflammatory liver diseases

Primary outcomes

1

Description
LDL-C
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

2

Description
HDL-C
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

3

Description
TG
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

4

Description
Total Cholestrol
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

5

Description
AST
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

6

Description
ALT
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

7

Description
Hepatic Steatosis
Timepoint
Beginning and end of the study
Method of measurement
Ultrasound

8

Description
hs-CRP
Timepoint
Beginning and end of the study
Method of measurement
ELISA

9

Description
GSH
Timepoint
Beginning and end of the study
Method of measurement
ELISA

10

Description
total antioxidant capacity
Timepoint
Beginning and end of the study
Method of measurement
ELISA

11

Description
FBS
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method using a kit

12

Description
HOMA-IR
Timepoint
Beginning and end of the study
Method of measurement
Calculation

13

Description
Weight
Timepoint
Beginning and end of the study
Method of measurement
Balance

14

Description
Body mass index
Timepoint
Begining and end of the study
Method of measurement
Calculation

15

Description
Leptin
Timepoint
Beginning and end of the study
Method of measurement
ELISA

16

Description
Lipopolysaccharides
Timepoint
Beginning and end of the study
Method of measurement
ELISA

17

Description
waist circumstance
Timepoint
Beginning and end of the study
Method of measurement
tape

Secondary outcomes

1

Description
Total Calorie Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

2

Description
Total Carbohydrate Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

3

Description
Total Protein Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

4

Description
Total Fat Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

5

Description
Total Fiber Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

6

Description
Total MUFA Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

7

Description
Total PUFA Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

8

Description
Total SFA Intake
Timepoint
Beginning and end of the study
Method of measurement
3- days Recall Questionnaire

Intervention groups

1

Description
Intervention group: for 12 weeks, 3-gram Spirulina per day from the Drotat high-tech and pharmaceutical science company in Iran.
Category
Treatment - Other

2

Description
Control group: for 12 weeks, 3-gram maltodextrin per day from the Drotat high-tech and pharmaceutical

science company in Iran.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani Hospital

Full name of responsible person

Amir Sadeghi

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Arabi Ave, Daneshjoo Blvd, Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahdi Shadnoush

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Associate professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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