Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

Evaluating the Effect of Spirulina Consumption on Anthropometric, Glucose, Lipid, Antioxidant, Inflammatory indices and Liver Enzymes in Non-Alcoholic Fatty Liver Patient.

Protocol summary

Study aim
Determination of the effect of Spirulina on anthropometric characteristics, inflammatory markers, oxidative stress, Homa index, blood pressure, lipid profile and liver enzymes in patients with fatty liver.

Design
A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct
The study population will be selected from patients with non-alcoholic fatty liver disease admitted to the clinics of Shiraz according to the inclusion criteria and the purpose and procedures for those eligible for inclusion will be fully explained and if applicable. The willingness of the study participants to complete the informed consent form will be completed. Participants were divided into two groups of intervention and control using block randomization

Participants/Inclusion and exclusion criteria
Non-alcoholic fatty liver disease, no malnutrition, no alcohol consumption, no blood lipid-lowering medication, no specific diets such as vegetarian and raw foods, no diabetes mellitus, cardiovascular disease, liver disease, no pregnancy and lactation, no drugs that cause fatty liver (methotrexate, tamoxifen, valproate, etc.)

Intervention groups
The intervention group will receive 2 grams of spirulina daily for 8 weeks and the control group will receive 2 grams of placebo daily for 8 weeks.

Main outcome variables
Anthropometric, glucose, lipid, antioxidant, inflammatory and liver enzymes indices

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200304046692N1**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **retrospective**

Last update: **2020-03-11, 1398/12/21**
Update count: **0**

Registration date
2020-03-11, 1398/12/21

Registrant information
Name
Reza Barati-Boldaji
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3225 7162
Email address
reza93barati@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-11, 1398/09/20

Expected recruitment end date
2020-01-30, 1398/11/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the Effect of Spirulina Consumption on

Anthropometric, Glucose, Lipid, Antioxidant, Inflammatory indices and Liver Enzymes in Non-Alcoholic Fatty Liver Patient.

Public title
Evaluating the effect of Spirulina in Non-alcoholic fatty liver patient.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with Non-alcoholic fatty liver disease
Exclusion criteria:
Individuals with malnutrition Individuals with alcohol consumption taking lipid-lowering drugs following special diets such as vegetarian or raw vegetarian diseases such as diabetes mellitus, cardiovascular disease, liver disease (cirrhosis, alcoholic liver disease, viral hepatitis, autoimmune hepatitis, primary biliary cirrhosis, biliary obstruction, hepatic injury induced by hereditary hemochromatosis drugs, sclerosis cholangitis, and α antisense deficiency), cancer, renal failure, celiac; being in pregnancy and lactation. taking Drugs that cause fatty liver (methotrexate, tamoxifen, valproate, etc.)
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of the two groups will be done by blocking method. The block size is set to 4 and all possible states for groups A and B are written and this is repeated until the number reaches 46. Then each component of the block is assigned a number using a random number table. The numbers given to each of the blocks represent the number assigned to each predefined number. This way the group assigned to each person is identified.
Blinding (investigator's opinion)
Double blinded
Blinding description
The designed placebo is completely similar in color to that of the intervention group. To help the blind, the researcher is assisted by someone who is not involved in the research process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqyatallah University of Medical Sciences
Street address
Mulla Sadra Street, Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
0
Approval date
2020-01-13, 1398/10/23
Ethics committee reference number
IR.BMSU.REC.1398.312

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
The degree of fatty liver
Timepoint
Before and after 8 weeks of intervention
Method of measurement
liver ultrasound

Secondary outcomes

1

Description
Anthropometric indices
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Digital scales and tape meters

2

Description
Lipid profile

Timepoint
Before and after 8 weeks of intervention
Method of measurement
Kit

3

Description
Systolic and diastolic blood pressure
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Mercury barometer

4

Description
Blood sugar indices
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Kit

5

Description
inflammatory indices
Timepoint
Before and after 8 weeks of intervention
Method of measurement
enzyme-linked immunosorbent assay(ELISA)kit

6

Description
Liver enzymes
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Kit

Intervention groups

1

Description
Intervention group: For 8 weeks, they will receive 2 grams of spirulina daily in form of the sauce prepared at the Shiraz Namakin Factory.Each 20g sauce sachet contains 2 grams of spirulina. At the beginning of the study, the number of sauces required will be delivered to each individual (30 sachets at the beginning of the first month and 30 sachets at the beginning of the second month). Individuals are asked to eat one sachet daily with food.
Category
Treatment - Other

2

Description
Control group: For 8 weeks, they will receive placebo daily in form of the sauce prepared at the Shiraz Namakin Factory with Edible color . At the beginning of the study, the number of sauces required will be delivered to each individual (30 sachets at the beginning of the first month and 30 sachets at the beginning of the second month). Individuals are asked to eat one sachet daily with food.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Clinic
Full name of responsible person
Reza Barati Boldaji
Street address
Namaz Square
City
Shiraz
Province
Fars
Postal code
0
Phone
+98 71 3612 2206
Email
reza93barati@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Younes Qasemi
Street address
Zand Blvd
City
Shiraz
Province
Fars
Postal code
0
Phone
+98 71 3612 2206
Email
reza93barati@gmail.con
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Reza Barati

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Khalili Blvd

City

Shiraz

Province

Fars

Postal code

0

Phone

+98 71 3612 2206

Email

reza93barati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Reza Barati

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Khalili Blvd

City

Shiraz

Province

Fars

Postal code

0

Phone

+98 71 3612 2206

Email

reza93barati@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Reza barati

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Khalili Blvd

City

Shiraz

Province

Fars

Postal code

0

Phone

+98 71 3612 2206

Email

reza93barati@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of the access period, 6 months after printing results

To whom data/document is available

For researchers working only in academic and scientific institutions

Under which criteria data/document could be used

For use in research and publication of articles

From where data/document is obtainable

Reza Barati 0098 9132807850

What processes are involved for a request to access data/document

Initially contacting the researcher and expressing the request then reviewing the request by the researcher and finally sending the documentation if the researcher agrees

Comments