

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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.com

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

