

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of food containing spirulina algae consumption on blood pressure, antropometric parameters, serum lipid profile and inflammation and oxidative stress indices on patients with hypertension

Protocol summary

Study aim

Determining effects of consumption of food containing spirulina algae on blood pressure, antropometric parameters, serum lipid profile and inflammation and oxidative stress indices on patients with hypertension

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 48 patients.
Randomization based on the method of reversible blocks

Settings and conduct

Place of the study in Fars province, Shiraz city

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Adults aged 24 to 65 years with 130 mmHg or more for Systolic blood pressure and 80 mmHg or more for Diastolic blood pressure were included
Exclusion criteria included: Any history of cardiovascular, hepatic, renal, inflammatory bowel disease, diabetes, and thyroid disorders.

Intervention groups

First group: Individuals receiving the product containing Spirulina
Second group (Control group): Individuals receiving the product without Spirulina

Main outcome variables

Blood pressure; Antropometric parameters; Serum lipid profile; Serum level of hs-CRP; Serum level of MDA.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200404046940N1**

Registration date: **2020-06-07, 1399/03/18**

Registration timing: **retrospective**

Last update: **2020-06-07, 1399/03/18**

Update count: **0**

Registration date

2020-06-07, 1399/03/18

Registrant information

Name

Zohreh Ghaem Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 8693

Email address

zohreh.ghaemfar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

2020-01-16, 1398/10/26

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-03-18, 1398/12/28

Scientific title

Effects of food containing spirulina algae consumption on blood pressure, antropometric parameters, serum lipid profile and inflammation and oxidative stress indices on patients with hypertension

Public title

Effects of Spirulina consumption on patients with hypertension

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Systolic blood pressure 130 mm Hg or more
Diastolic blood pressure 80 mm Hg or more
Both of the above
Between the age of 24 and 65 years

Exclusion criteria:

Suffering from cardiovascular, liver, kidney, inflammatory bowel disease, diabetes and thyroid disorders
History of cardiac surgery
Weight loss of more than 5% in the last 3 months
Participate in other studies in the last 6 months
Use any supplements or diets
Pregnancy and lactation
History of inflammation in the past two weeks (including infection, fracture, etc.)

Age

From **24 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization based on the method of reversible blocks
In this scheme, randomization based on the method of reversible blocks is carried out in the way that 4 blocks of 12 people will be created. These blocks are then randomly placed in two rows, male and female. Through classifying blocks by the gender, at the end of sampling we will have an equal number of male and female participants in both groups (A and B), thereby modifying the effect of gender distortion.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the first step is to allocate a specific pilot that will be used to produce products containing Spirulina and without Spirulina in a factory and will be monitored by the project scientific consultant (food industry specialist) and the researcher to ensure optimal production conditions. After that, the factory is asked to produce a sufficient number of products in the same packaging and different labels A or B. Consultant of the project and production manager are the only people who are aware of the type of packaged products. As a result, the researcher and participants will be blinded. The products are delivered from the factory after production and are given to the patients immediately. In order to concealment, all code predicted by random allocation software is placed in pockets respectively. Pockets related to a women's accidental block are placed in the first box and pockets related to a men's accidental block are placed in the second box. The lids of the boxes are

designed so that only the top pocket can be removed each time. The first pocket taken from the women's box will be assigned to the first female client, who will determine which group (A or B) this person will be after opening. The same goes for men. By doing so, the researcher cannot predict which group the next clients will fall into and the interviewer's bias will be curbed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Science

Street address

Central building of Shiraz University of Medical Sciences
Zand St.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-01-15, 1398/10/25

Ethics committee reference number

IR.SUMS.REC.1398.1193

Health conditions studied

1

Description of health condition studied

Primary Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

Measurement of blood pressure before and 60 days after the intervention

Method of measurement

Digital Arm Sphygmomanometer

2

Description

Serum lipid profile

Timepoint

Before and 60 days after the intervention

Method of measurement

By the means of Pars Azmoon Company kit and auto analyzer BT 1500

3

Description

hs-CRP (high-sensitivity C-reactive protein)

Timepoint

Before and 60 days after the intervention

Method of measurement

By Enzyme-linked immunosorbent assay (ELISA) kit

4

Description

Malondialdehyde

Timepoint

Before and 60 days after the intervention

Method of measurement

Thiobarbituric acid method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving the food product containing spirulina algae would use the product containing 2 grams of Spirulina per day up to 2 months. The products were produced in Tiondasht Keshto Sanaat company

Category

Treatment - Devices

2

Description

Control group: The group receiving the food without Spirulina algae

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Professor Kojuri clinic

Full name of responsible person

Mohammad Hosein Rahmani

Street address

Niayesh Blvd, Chamran Blvd, Shiraz

City

Shiraz

Province

Fars

Postal code

7189793167

Phone

+98 71 3654 0068

Email

info@kojurclinic.com

Web page address

http://kojurclinic.com/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3212 2884

Fax

+98 71 3235 6996

Email

info@sums.ac.ir

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

Zohreh Ghaem Far

Position

Student of master of science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Unit 10, Floor 4, Pakdaman Bldg, 17th Alley, Felestin St, Khajeh Ata Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7916785418

Phone

+98 76 3334 8693

Email

zohreh.ghaemfar@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Ghaem Far

Position

Student of master of science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Unit 10, Floor 4, Pakdaman Bldg, 17th Alley, Felestin St, Khajeh Ata Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7916785418

Phone

+98 76 3334 8693

Email

zohreh.ghaemfar@gmail.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Ghaem Far

Position

Student of master of science

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Unit 10, Floor 4, Pakdaman Bldg, 17th Alley, Felestin St, Khajeh Ata Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7916785418

Phone

+98 76 3334 8693

Email

zohreh.ghaemfar@gmail.com

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

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I haven't decided yet. The release schedule is not clear yet.

When the data will become available and for how long

I haven't decided yet. The release schedule is not clear yet.

To whom data/document is available

I haven't decided yet. The release schedule is not clear yet.

Under which criteria data/document could be used

I haven't decided yet. The release schedule is not clear yet.

From where data/document is obtainable

I haven't decided yet. The release schedule is not clear yet.

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

I haven't decided yet. The release schedule is not clear yet.

Comments