

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of spirulina and chitosan supplementation along with eight weeks of combined exercises on blood pressure and lipid profile in hypertensive women.

Protocol summary

Study aim

Determining the effect of spirulina and chitosan supplementation along with eight weeks of combined exercises on blood pressure and lipid profile in women with hypertension

Design

Clinical trial with control group, with parallel groups, randomized, on 40 patients. Randomization by the method of equal blocks (10 blocks of 4) in which a number of intervention people and a number of comparison people are included in each block.

Settings and conduct

Eligible people were identified by referring to Prophets Hospital in Tehran and were placed in the intervention groups using equal blocks randomization (10 blocks of 4). Then, people will go to the sports club for training intervention and perform exercises and supplements for 8 weeks. And before and 24 hours after exercise interventions, blood samples are taken from people to be measured in the laboratory.

Participants/Inclusion and exclusion criteria

Entry requirements: suffering from high blood pressure
Conditions of non-entry: inability to practice

Intervention groups

Group of combined and complementary exercises: in the group of combined exercises, the samples perform aerobic and resistance exercises, and the supplementary groups also take spirulina and chitosan supplements. The control group is not subjected to any intervention.

Main outcome variables

High blood pressure; Lipid profile (triglycerides, cholesterol, etc.)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221120056548N2**

Registration date: **2022-11-30, 1401/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-30, 1401/09/09**

Update count: **0**

Registration date

2022-11-30, 1401/09/09

Registrant information

Name

Saeid Shamlou kazemi

Name of organization / entity

Bu-Ali Sina university

Country

Iran (Islamic Republic of)

Phone

+98 912 859 7297

Email address

saeidshamlou9092@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-24, 1401/09/03

Expected recruitment end date

2022-12-24, 1401/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of spirulina and chitosan supplementation

along with eight weeks of combined exercises on blood pressure and lipid profile in hypertensive women.

Public title

Effect of exercise, chitosan and spirulina on high blood pressure

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having high blood pressure

Exclusion criteria:

History of cardiovascular disease

Age

From **50 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomization, the method of equal blocks (10 blocks of 4) has been used, in which a number of intervention people and a number of comparison people are included in each block, and we have allocated them to different groups. The method and tool of block random sequence generation has been done using <https://www.sealedenvelope.com/simple-randomiser/v1/lits>.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sport Sciences Research Institute

Street address

Fifth Alley, Mir Emad Ave., Ostad Motahari Ave

City

Tehran

Province

Tehran

Postal code

1474674646

Approval date

2022-01-02, 1400/10/12

Ethics committee reference number

IR.SSRI.REC.1400.1291

Health conditions studied**1****Description of health condition studied**

Hypertensive diseases

ICD-10 code

I10-I15

ICD-10 code description

Hypertensive crisis

Primary outcomes**1****Description**

The percentage of people whose blood pressure has decreased.

Timepoint

Blood pressure measurement before and after the intervention

Method of measurement

Using a mercury sphygmomanometer (ALPK2) made in Japan

2**Description**

The percentage of people whose cholesterol, low-density lipoprotein and triglyceride levels have decreased.

Timepoint

Measurement of lipid profile before and after the intervention

Method of measurement

By testing blood samples

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: The exercise intervention in this research will be 8 weeks of combined aerobic and resistance exercises. 3 days a week (Saturday-Monday-Wednesday) from 5 to 6 in the evening by the subject. Aerobic training includes 30 minutes of non-stop walking from the first to the fourth week with an intensity of 40% of the maximum heart rate (MHR) 1 and from the fourth to the eighth week of the study with an intensity of 60% of the maximum heart rate (MHR), then warming up between the two exercises 10 repetitions of a movement and after 5 minutes 1RM2

test will be done and then resistance exercises will be done. Resistance exercises will be 30 minutes in the first 4 weeks with 40% intensity of a maximum repetition ("using 2 or 3 kg dumbbells and elastic resistance bands with yellow color (low intensity) of the brand ("RACINESS") and in the second 4 weeks with an intensity of 60% one maximum repetition ("using 4 or 5 kg dumbbells and resistance bands with blue color (medium intensity) brand RACINESS") are performed in 3 sets with 12 repetitions and 90 seconds rest between each set and 120 seconds between each exercise. Resistance exercises include horizontal leg press - rowing from the bottom (Low Row) - exercises Sitting with a chair (extensor chair) is a bench press exercise (chest and head). The supplement group also consumes 4.5 grams of spirulina supplement daily eensea.ir (provided by Danish Gulf Algae Technology Development Company), will be consumed by subjects in the form of 7 capsules of 600 mg per day. Chitosan supplement in the amount of 2 capsules in the specified dose of Karen company, each 500 mg before meals, is used by the subjects in the designated group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of the Prophets

Full name of responsible person

Saeid shamlou kazemi

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Abazar Blvd, Ayatollah Kashani Blvd, Second Sadeghieh Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Danesh Alborz University

Full name of responsible person

Saeid Shamlou Kazemi

Street address

Bu-Ali Sina University, Shahid Mostafa Ahmadi Roshan Street, Hamedan

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Hamadan

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6517838695

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Danesh Alborz University

Proportion provided by this source

10

Public or private sector

Private

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

Bu-Ali Sina University

Full name of responsible person

Saeid Shamlou Kazemi

Position

Student

Latest degree

Master

Other areas of specialty/work

Sport Medicine

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Person responsible for updating data

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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

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the intellectual rights are preserved, the data can be sent to the researchers.

From where data/document is obtainable

Email address:saeidshamlou9092@gmail.com

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

Submission of a written request (one week)

Comments