Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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/lists.
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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Position

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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