Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compatibility of hemodynamic and biochemical markers related to high blood pressure of older men; a long period of resistance training and consumption of saffron

Protocol summary

Study aim
The effect of long-term resistance training and saffron consumption on hemodynamic and biochemical markers related to high blood pressure of older men

Design
volunteers first register and then subjects selected purposefully based on inclusion criteria, and randomly divided into Four groups of resistance training, saffron, resistance training + saffron and control.

Settings and conduct
Subjects in resistance training groups and saffron + resistance training groups performed the resistance training protocol for twelve weeks (3 days per week). also Subjects in the saffron and resistance training + saffron groups consumed one tablet (200 mg) of saffron daily for twelve weeks.Blood pressure and blood sampling were measured in several stages.

Participants/Inclusion and exclusion criteria
The criteria for including the subjects were primary hypertension; absence of heart disease which prevented exercise; and absence of diabetes. Also, they had no history of performing regular exercise in the six months leading up to the study, and their systolic blood pressure ranged from 140-159 mm Hg and diastolic blood pressure lied within the range of 90-99 mm Hg .

Intervention groups
Four groups of resistance training, saffron, resistance training + saffron and control

Main outcome variables
Effect of resistance training and saffron consumption on blood pressure; ANP; CD25; Nitric Oxide; Adiponectin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190731044398N1**
Registration date: **2019-08-15, 1398/05/24**
Registration timing: **retrospective**

Last update: **2019-08-15, 1398/05/24**
Update count: **0**

Registration date
2019-08-15, 1398/05/24

Registrant information

Name
Babak Hooshmand Moghadam

Name of organization / entity
Ferdowsi University of Mashhad

Country
Iran (Islamic Republic of)

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+98 51 3881 0540

Email address
babak.hooshmand@mail.um.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-07-11, 1398/04/20

Actual recruitment start date
2019-04-09, 1398/01/20

Actual recruitment end date
2019-07-11, 1398/04/20

Trial completion date
2019-07-11, 1398/04/20

Scientific title
Compatibility of hemodynamic and biochemical markers related to high blood pressure of older men; a long

period of resistance training and consumption of saffron

Public title
Compatibility of hemodynamic and biochemical markers related to high blood pressure of older men; a long period of resistance training and consumption of saffron

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
The criteria for including the subjects were primary hypertension absence of heart disease which prevented exercise, and absence of diabetes They had no history of performing regular exercise in the six months leading up to the study Their systolic blood pressure ranged from 140-159 mm Hg and diastolic blood pressure lied within the range of 90-99 mm Hg

Exclusion criteria:
Participation in exercise training programs other than the exercise training program of the present study

Age
From **50 years** old to **70 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Actual sample size reached: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize, simple randomization method with random number Table method was used. This table contains a bunch of numbers that are randomly drawn in the form of a table without a specific pattern and order. The numbers directions(Left, right, up, down) were first determined by the researcher to read the numbers and then the numbers were considered for different research groups. In the next step, the researcher randomly placed on one of the numbers and moved in the present direction and recorded the numbers for that direction in the target group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this research, participants are unaware of the group assigned to themselves and other participants. A separate workout hour is considered for each intervention group. experts in laboratory analysis are also unaware of the type of intervention and the participating groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Physical Education and Sport Sciences

Street address
impasse 5, district 7, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1587958711

Approval date
2019-03-11, 1397/12/20

Ethics committee reference number
IR.SSRC.REC.1398.020

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood Pressure

Timepoint
Before and 2، 4، 6، 8، 10، 12، 14، 16، 18 weeks after intervention

Method of measurement
Blood pressure mannometer (mmHg)

2

Description
Serum levels of ANP

Timepoint
Before and 6، 12، 18 weeks after intervention

Method of measurement
Blood sampling and using ELISA method

3

Description
Serum levels of CD25

Timepoint

Before and 6، 12، 18 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

4

Description

Serum levels of nitric acid

Timepoint

Before and 6، 12، 18 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

5

Description

Serum levels of adiponectin

Timepoint

Before and 6، 12، 18 weeks after intervention

Method of measurement

Blood sampling and using ELISA method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The training group performed 12 weeks and each week 3 sessions of resistance training.

Category

Other

2

Description

Intervention group: The saffron group consumed 200 mg of saffron for 12 weeks.

Category

Other

3

Description

Intervention group: The saffron + training group performed resistance training program for 12 weeks and 3 sessions per week and consumed 200 mg saffron daily.

Category

Other

4

Description

Control group: The control group did not perform resistance training and did not consume saffron.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Tehran

Full name of responsible person

Babak Hooshmand Hoghadam

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Faculty of Physical Education and Sport Science of Tehran University, Northern Kargar Ave, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, University of Tehran

Full name of responsible person

Fetemeh Shabkhiz

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Faculty of Physical Education and Sport Science of Tehran University, Northern Kargar Ave, Tehran, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology, University of Tehran

Proportion provided by this source

100

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

University of Tehran

Full name of responsible person

Fetemeh Shabkhiz

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Tehran

Full name of responsible person

Fetemeh Shabkhiz

Position

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Latest degree

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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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Personal information of patients is confidential. But access to the research method and the information obtained from the research is not a problem

When the data will become available and for how long

After printing in a journal

To whom data/document is available

All students and enthusiasts

Under which criteria data/document could be used

In order to use data to carry out research work in this area

From where data/document is obtainable

The authors of this article b.hooshmand.m@gmail.com

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

By sending email the author will work with the applicant as soon as possible

Comments