

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

###### Phone

+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 science

#### 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 manometer (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 Haghdam

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614418

**Phone**

+98 21 8835 1730

**Email**

b.hooshmand.m@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Deputy of Research and Technology, University of Tehran

**Full name of responsible person**

Fetemeh Shabkhiz

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1417614418

**Phone**

+98 21 8835 1730

**Email**

shabkhiz@ut.ac.ir

**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

**Street address**

Faculty of Physical Education and Sport Sciences,  
Tehran University , North Kargar Ave, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۷۶۱۴۴۱۸

**Phone**

+98 21 8835 1730

**Email**

shabkhiz@ut.ac.ir

**Person responsible for scientific 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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**Phone**

+98 21 8835 1730

**Email**

shabkhiz@ut.ac.ir

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

Ferdowsi University of Mashhad

**Full name of responsible person**

Babak Hooshmand Hoghdam

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Physiology

**Street address**

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

**City**

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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**