

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Responses of plasma volume changes and hematological factors to two different isometric protocols in men with high blood pressure

#### Protocol summary

##### Study aim

Investigating the response of hematological and hemodynamic factors to two different isometric protocols in men with high blood pressure

##### Design

The number of 10 subjects, based on their grouping, performed both high-intensity and low-intensity protocols in a counter balance manner.

##### Settings and conduct

Ten middle-aged men with high blood pressure without any other underlying illnesses with a range of 30-60 years were randomly selected. The training program included two high-intensity and low-intensity isometric handgrip (IHG) protocols. The high intensity protocol includes 8 repetitions of 30 seconds with 60% maximum voluntary contraction (MVC) with 2 minutes of rest between repetitions and the low-intensity protocol consisted of 4 repetitions of 2 minutes at 30% of MVC with 4 minutes of rest between repetitions. Three blood samples were taken before and immediately after exercise and after 20 min of recovery, and were analyzed for lactate, fibrinogen, hemoglobin and hematocrit were measured and Plasma volume changes were calculated by using the hematocrit and hemoglobin. Blood pressure and heart rate were measured at rest, immediately after exercise and at 5,10,15,30,45 and 60 minutes during recovery.

##### Participants/Inclusion and exclusion criteria

Ten men with primary hypertension without a history of regular sports activity with an age range of 40 to 60 years. The subjects did not use any drugs affecting cardiovascular function, especially antihypertensive drugs. Also, the subjects did not use cigarettes, alcohol and any substance that affects blood pressure.

##### Intervention groups

High intensity protocol training group - Low intensity protocol training group

##### Main outcome variables

Although the isometric exercise induced significant

changes in blood pressure, plasma volume changes and hematological variables, these changes are not acutely intensity related.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220728055573N1**

Registration date: **2022-08-08, 1401/05/17**

Registration timing: **prospective**

Last update: **2022-08-08, 1401/05/17**

Update count: **0**

##### Registration date

2022-08-08, 1401/05/17

##### Registrant information

##### Name

Alireza Jowhari

##### Name of organization / entity

Shahid Beheshti University of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5336 3847

##### Email address

afjf2020@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-12, 1401/05/21

##### Expected recruitment end date

2022-09-20, 1401/06/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Responses of plasma volume changes and hematological factors to two different isometric protocols in men with high blood pressure

**Public title**

Isometric exercises and blood flow indicators in patients with high blood pressure

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

In the high blood pressure stage, the blood pressure level is 140 or above 140 mm Hg Age range is between 40 and 60 years old The gender of all the subjects is male

**Exclusion criteria:**

Having regular exercise

**Age**

From **40 years** old to **60 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **10**

More than 1 sample in each individual

Number of samples in each individual: **2**

Samples responding to two training models

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, by examining the files of patients with high blood pressure referred to Shahid Rajaei Heart Hospital, the subjects who were eligible to enter the research were selected and after a phone call or face-to-face meeting and obtaining their consent, they were selected to participate in the research. After measuring the blood pressure, the subjects were placed in double blocks (five blocks) based on the blood pressure level from the highest to the lowest. Then two subjects of each block were randomly divided into two groups (low intensity protocol and high intensity protocol). In the end, 10 subjects were placed in each group and the subjects with higher blood pressure were divided into both groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Shahid Beheshti University of Tehran

**Street address**

Shahid Shahriari Square, Evin, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983969411

**Approval date**

2018-08-11, 1397/05/20

**Ethics committee reference number**

IR.SBU.ICBS.97/1024

**Health conditions studied****1****Description of health condition studied****ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Viscosity of blood and plasma

**Timepoint**

Before training and immediately after the training session

**Method of measurement**

EDTA blood sample and using a viscometer

**2****Description**

Hematocrit, hemoglobin, fibronogen, lactate

**Timepoint**

Before training and immediately after the training session

**Method of measurement**

Using a special diagnostic kit for each agent

**3****Description**

Systolic, diastolic blood pressure

**Timepoint**

before training, immediately after training and 5, 10, 15, 30, 45 and 60 minutes after training

## Method of measurement

Digital blood pressure monitor

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: 10 male subjects with high blood pressure, based on their grouping in the counter balance method, performed each of the two high-intensity or low-intensity protocols with their non-dominant hand. The interval between each exercise was 48 hours.

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Rajaei Heart Hospital

#### Full name of responsible person

Mohsen Javidi

#### Street address

The intersection of Waliar and Niayesh streets

#### City

Tehran

#### Province

Tehran

#### Postal code

1115119969

#### Phone

+98 21 2990 2931

#### Email

javidi68@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University

#### Full name of responsible person

Babak Shokri

#### Street address

Shahid Shahriari Square, Evin, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

1983969411

#### Phone

+98 21 2990 2236

#### Email

b-shokri@sbu.ac.ir

### Grant name

N/A

### Grant code / Reference number

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

Yes

### Title of funding source

Shahid Beheshti University

### 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

Shahid Beheshti University

#### Full name of responsible person

Sajjad Ahmadizad

#### Position

Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiology of exercise

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Shahid Shahriari Square, Evin, Tehran

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University

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Sajjad Ahmadizad

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Professor

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**Person responsible for updating data**

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**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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

N/A

**When the data will become available and for how long**

N/A

**To whom data/document is available**

N/A

**Under which criteria data/document could be used**

N/A

**From where data/document is obtainable**

N/A

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

N/A

**Comments**