

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Waliasr and Niayesh streets

City

Tehran

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1115119969

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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

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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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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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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