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 Waliasr 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
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1983969411
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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
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Other areas of specialty/work
Physiology of exercise
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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