

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the effect of 8 weeks of resistance training with and without blood flow restriction on hypoxia-inducible factor-1 (HIF-1a), vascular endothelial growth factor, nitric oxide and endothelin-1 in men with prehypertension.

Protocol summary

Study aim

Comparison of the effect of 8 weeks of resistance training with and without blood flow restriction on hypoxia-inducible factor-1 (HIF-1a), vascular endothelial growth factor, nitric oxide and endothelin-1 in men with prehypertension.

Design

A total of 36 men (age=30-45 years) will voluntarily participate in this quasi-experimental research with pretest-posttest control group design.

Settings and conduct

The subjects are randomly assigned into three groups: high intensity resistance training without blood flow restriction group, low intensity resistance training with blood flow restriction group, and low intensity resistance training without blood flow restriction group (control group). The exercises are performed for 8 weeks, 3 sessions per week, in Ilam City. Before training and after training program, blood samples are taken from all subjects and blood pressure measurements will be performed.

Participants/Inclusion and exclusion criteria

The research inclusion criteria are men with prehypertension, being physically and mentally healthy, having no history of regular sport activity during the previous two years, and giving informed personal consent to participate in the study. The research exclusion criteria are: Having cardiovascular, oncological, hormonal, and any acute or chronic diseases, being addicted to drugs and cigarettes, and having medication intake.

Intervention groups

1. High intensity resistance training without blood flow restriction group, 2. Low intensity resistance training with blood flow restriction group, 3. Low intensity resistance training without blood flow restriction group

(control).

Main outcome variables

Hypoxia-inducible factor-1 (HIF-1a): vascular endothelial growth factor: nitric oxide: endothelin-1.

General information

Reason for update

Acronym

BFR

IRCT registration information

IRCT registration number: **IRCT20220501054712N1**

Registration date: **2023-09-25, 1402/07/03**

Registration timing: **prospective**

Last update: **2023-09-25, 1402/07/03**

Update count: **0**

Registration date

2023-09-25, 1402/07/03

Registrant information

Name

Ali Yari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3334 8077

Email address

aliyari9090@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-11-06, 1402/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 8 weeks of resistance training with and without blood flow restriction on hypoxia-inducible factor-1 (HIF-1a), vascular endothelial growth factor, nitric oxide and endothelin-1 in men with prehypertension.

Public title

Comparison of the effects of two types of resistance training on hypoxia-inducible factor-1 (HIF-1a), vascular endothelial growth factor, nitric oxide and endothelin-1.

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Men with prehypertension Physical and mental health Having no history of regular sport activity during the previous two years Informed personal consent to participate in the study

Exclusion criteria:

Having no cardiovascular diseases Having no oncological diseases Having no hormonal diseases Having no acute or chronic diseases Not being addicted to drugs and cigarettes No medication intake

AgeFrom **30 years** old to **45 years** old**Gender**

Male

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **36****Randomization (investigator's opinion)**

Randomized

Randomization description

A simple randomization method is used in this study. Randomization is run using random number tables. A table of random digits is a set of numbers that have been generated fully randomly without any pattern or specified order, and tabulated. First, an identifying number is assigned to each subject. This way, each person is identified by a number from 00 to 35. The researcher then randomly divides these numbers between three groups: intervention and control groups using a random digits table as follows. Upon the attendance of subjects, the researcher starts to read the numbers of the table. The subjects are assigned to the groups as follows: The first read identification number between 00 and 35 is assigned to the first intervention group (obstructive training group), the second number to the second intervention group (without obstructive

training group), and the third number to the control group. This number assignment continues until 12 subjects are assigned to each group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Islamic Azad University Kermanshah Branch

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Farhikhtegan Blvd., Ferdowsi Sq., Kermanshah

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Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.IAU.KSH.REC.1402.068

Health conditions studied**1****Description of health condition studied**

primary hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes**1****Description**

Hypoxia-inducible factor-1 (HIF-1a)

Timepoint

The tests will be done in two stages: one day before the first training session (pre-test) and 48 hours after the last training session (post-test), on the 8th week of training and after 10-12 hours of fasting.

Method of measurement

After samples coagulation and serum centrifugation, the serum levels of variables are determined using the ELISA method.

2

Description

Vascular endothelial growth factor

Timepoint

The tests will be done in two stages: one day before the first training session (pre-test) and 48 hours after the last training session (post-test), on the 8th week of training and after 10-12 hours of fasting.

Method of measurement

After samples coagulation and serum centrifugation, the serum levels of variables are determined using the ELISA method.

3

Description

Nitric oxide

Timepoint

The tests will be done in two stages: one day before the first training session (pre-test) and 48 hours after the last training session (post-test), on the 8th week of training and after 10-12 hours of fasting.

Method of measurement

After samples coagulation and serum centrifugation, the serum levels of variables are determined using the ELISA method.

4

Description

Endotelin-1

Timepoint

The tests will be done in two stages: one day before the first training session (pre-test) and 48 hours after the last training session (post-test), on the 8th week of training and after 10-12 hours of fasting.

Method of measurement

After samples coagulation and serum centrifugation, the serum levels of variables are determined using the ELISA method.

Secondary outcomes

1

Description

Blood pressure

Timepoint

two months

Method of measurement

Measurements will be done in two stages: one day before the first training session (pre-test) and 48 hours after the last training session (post-test), on the 8th week of training using pressure gauge device.

Intervention groups

1

Description

Intervention group 1: the high intensity resistance training without blood flow restriction for 8 weeks, 3

sessions per week with an intensity of 75% of one rep-max.

Category

Other

2

Description

Intervention group 2: the low intensity resistance training with blood flow restriction for 8 weeks, 3 sessions per week with an intensity of 30% of one rep-max.

Category

Other

3

Description

Intervention group 3: the low intensity resistance training without blood flow restriction for 8 weeks, 3 sessions per week with an intensity of 30% of one rep-max (control group).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ilam University of Medical Sciences

Full name of responsible person

Ali yari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

Proportion provided by this source

10

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**

Islamic Azad University

Full name of responsible person

Ali Yari

Position

Employee

Latest degree

Master

Other areas of specialty/work

Others

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available