

# 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-1 $\alpha$ ), 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-1 $\alpha$ ), 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-1 $\alpha$ ): 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

**Age**From **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

**Street address**

Farhikhtegan Blvd., Ferdowsi Sq., Kermanshah

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

۶۷۱۸۹۹۷۵۵۱

**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

#### **Street address**

No. 17, Unit 17, Block 5, Milad Building, Daneshjoo Blvd.,

#### **City**

Ilam

#### **Province**

Ilam

#### **Postal code**

6931994565

#### **Phone**

+98 918 343 6046

#### **Email**

Aliyari9090@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Islamic Azad University

#### **Full name of responsible person**

Morteza Kahrarian

#### **Street address**

Farhikhtegan Blvd., Ferdowsi Sq., Kermanshah

#### **City**

Kermanshah

#### **Province**

Kermanshah

**Postal code**

۶۷۱۸۹۹۷۵۵۱

**Phone**

+98 83 3724 3181

**Email**

Info@iauksh.ac.ir

**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

**Street address**

No. 17, Unit 17, Block 5, Milad Building, Daneshjoo Blvd.,

**City**

Ilam

**Province**

Ilam

**Postal code**

693994565

**Phone**

+98 918 343 6046

**Email**

Aliyari9090@yahoo.com

**Person responsible for scientific 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**

Physiology

**Street address**

No. 17, Unit 17, Block 5, Milad Building, Daneshjoo Blvd.,

**City**

Ilam

**Province**

Ilam

**Postal code**

6931994565

**Phone**

+98 918 343 6046

**Email**

Aliyari9090@yahoo.com

**Person responsible for updating data****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**

Physiology

**Street address**

No. 17, Unit 17, Block 5, Milad Building, Daneshjoo Blvd.,

**City**

Ilam

**Province**

Ilam

**Postal code**

6931995465

**Phone**

+98 918 343 6046

**Email**

Aliyari9090@yahoo.com

**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