Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 endotelin-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 endotelin-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؛ endotelin-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)

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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 endotelin-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
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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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No. 17, Unit 17, Block 5, Milad Building, Daneshjoo Blvd.,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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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