

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of 12 weeks of aerobic and resistance exercise on hemodynamic, biochemical and functional factors in women with hypertension

Protocol summary

Study aim

The effect of 12 weeks of aerobic and resistance exercise on hemodynamic, biochemical and functional factors in women with hypertension

Design

A randomized clinical trial study, single-blind, Parallel, 45 participants randomized to 2 intervention groups and a control group through web-based randomization.

Settings and conduct

Participants were equally divided into three groups: aerobic, isometric, handgrip and control. This is a blind study that evaluators are about blind intervention. This study is performed in Alzahra Cardiovascular Hospital in Shiraz. Individuals in each group perform the exercise in 3 session for 12 weeks. In order to measure the effects of exercise on the hemodynamic, biochemical and function factors of women with hypertension are measured before and after 12 weeks.

Participants/Inclusion and exclusion criteria

1-women with 35-55 years 2-premenopausal 3-regularly menstruating 4-free of any chronic, cardiovascular, metabolic, renal or respiratory disease 5-No physical and functional limitations 6-non-smokers 7-the Patient with high blood pressre (pre to stage 1 hypertension)

Intervention groups

3 groups: 1-high intensity interval training group: four intervals 4-minute with 85-95% of HR peak with 3 minutes of active rest between intervals of approximately 70% HR peak in 3 session for 12 weeks 2-isometric handgrip exercise group: four isometric handgrip contractions 2minute with non-dominant hand in 30% intensity of maximum voluntary contraction with a 2-minute break between contractions in 3 session for 12 weeks 3-control group: did not perform any specific

Main outcome variables

Cortisol, Nitric Oxide, Endothelin-1, Total Antioxidant Capacity, Reactive oxygen species, Peripheral Vascular

Resistance, Endothelial-dependent vasodilation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191123045478N1**

Registration date: **2020-12-16, 1399/09/26**

Registration timing: **prospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **0**

Registration date

2020-12-16, 1399/09/26

Registrant information

Name

Elham Shakoor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-22, 1399/10/02

Expected recruitment end date

2021-02-23, 1399/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of 12 weeks of aerobic and resistance exercise on hemodynamic, biochemical and functional factors in women with hypertension

Public title

The effect of 12 weeks of aerobic and resistance exercise on blood pressure

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

the Patient with high blood pressure (pre to stage 1 hypertension) premenopausal free of any chronic, cardiovascular, metabolic, renal or respiratory disease No physical and functional limitations non-smokers Age between 33 to 55 years

Exclusion criteria:

use of any medications that may affect blood pressure and cardiovascular responses regular exercise within the last six months history of myocardial infarction and angioplasty abnormalities of ECG, echo, and stress test

Age

From **33 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomized into one of three groups (Two intervention and one control) using an online randomization system (randomizer.org). A member of the research team who is not involved in the selection of samples will determine the randomization sequence using a computer program. Participants will be notified of their group allocation with a sealed envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor is blind to the groups' randomization and interventions receiving by participants. in this way, during the evaluation before and after the intervention protocol, they do not make mistakes in their judgments in favor of a specific therapeutic intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical Committee of Shiraz University of Medical Science

Street address

5th Floor, Central building of Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.SUMS.MED.REC.1399.178

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

Blood Pressure

ICD-10 code

R03

ICD-10 code description

Abnormal blood-pressure reading, without diagnosis

2**Description of health condition studied**

Aerobic Exercise

ICD-10 code

Y93.A3

ICD-10 code description

Activity, aerobic and step exercise

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

Cortisol

Timepoint

Before and after intervention

Method of measurement

With ELISA kit

2**Description**

Nitric Oxide

Timepoint

Before and after intervention

Method of measurement

With ELISA kit

3

Description

Endothelin-1

Timepoint

Before and after intervention

Method of measurement

With ELISA kit

4

Description

Total Antioxidant Capacity

Timepoint

Before and after intervention

Method of measurement

With ELISA kit

5

Description

Reactive oxygen species

Timepoint

Before and after intervention

Method of measurement

With ELISA kit

6

Description

Peripheral Vascular Resistance

Timepoint

Before and after intervention

Method of measurement

with Doppler ultrasonography

7

Description

Endothelial-dependent vasodilation

Timepoint

Before and after intervention

Method of measurement

with Doppler ultrasonography

Secondary outcomes

1

Description

Systolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Digital Aneroid Sphygmomanometer Measure

2

Description

diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Digital Aneroid Sphygmomanometer Measure

3

Description

Mean arterial pressure

Timepoint

Before and after intervention

Method of measurement

Digital Aneroid Sphygmomanometer Measure

4

Description

Heart rate

Timepoint

Before and after intervention

Method of measurement

Digital Aneroid Sphygmomanometer Measure

Intervention groups

1

Description

Control group without exercise or Intervention:
Participants in this group will have no exercise during the study

Category

Treatment - Other

2

Description

Intervention group high intensity interval Aerobic training: Participants do aerobic exercise for one session . The duration of each session is 40 minutes, including pre-workout warm-up, aerobic exercise program, and post-workout cooling.

Category

Treatment - Other

3

Description

Intervention group and isometric handgrip training: Participants do isometric handgrip exercise for one session . The duration of each session is 40 minutes, including pre-workout warm-up, aerobic exercise program, and post-workout cooling.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart Hospital, Shiraz

Full name of responsible person

Dr. Payman Izadpanah

Street address

Sibooye Blvd, Al-Zahra Heart Hospital,

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address<http://research.sums.ac.ir/fa/index.html>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

30

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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Payman Izadpanah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data can publish for publishing paper

When the data will become available and for how long

The study protocol will be available after publishing the paper

To whom data/document is available

everyone

Under which criteria data/document could be used

For future studies

From where data/document is obtainable

Via email

What processes are involved for a request to access data/document

The applicant needs to introduce his/her and need to explain the purpose of request as well. The information will send you as soon as possible.

Comments