

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of 12 weeks of aerobic exercise on a selection of symptoms of heart failure in women patients with hypertension

#### Protocol summary

##### Study aim

Explain the effect of 12 weeks of aerobic exercise on a selection of symptoms of heart failure in female patients with hypertension.

##### Design

A clinical trial with control and practice group, one-way, random and available was used on 35 patients

##### Settings and conduct

First, the researcher refers to Rasool Akram clinic and explains the purpose of the research to the officials. Then, with the consent of the officials, the eligible people are selected and a briefing session is held for them. The type of exercise, exercise program, steps of measuring blood pressure and heart rate in each session, the method and time of blood sampling and the results of the research are explained. Then the subjects are homogeneously divided in terms of age, weight and in 2 groups (1 control group and 1 experimental group) and the experimental group for 12 consecutive weeks in a sports training program in the gym of the Department of Physical Education located on Imam Street Khomeini Abdanan participates. In aerobic exercise, each exercise session consists of three parts: warming up, the main stage and cooling down.

##### Participants/Inclusion and exclusion criteria

1- Their age was between 50 and 70 years. 2- They had high blood pressure. 3- They had no history of heart and balloon surgery. 4- They were not diabetic. 5. They were non-athletes.

##### Intervention groups

The aerobic exercise program consisted of 12 weeks of aerobic exercise, 3 sessions per week and each session lasted 45 minutes, and the control group engaged in their normal daily activities during this time and did not engage in any exercise.

##### Main outcome variables

CT-1 variables; TGF-B1; NT-proBNP and systolic and diastolic blood pressure; Aerobic activity week

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200815048410N1**

Registration date: **2020-08-18, 1399/05/28**

Registration timing: **retrospective**

Last update: **2020-08-18, 1399/05/28**

Update count: **0**

##### Registration date

2020-08-18, 1399/05/28

##### Registrant information

##### Name

somayeh abedzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3362 4252

##### Email address

s.abedzade89@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2018-12-22, 1397/10/01

##### Trial completion date

2018-12-22, 1397/10/01

##### Scientific title

The effect of 12 weeks of aerobic exercise on a selection of symptoms of heart failure in women patients with hypertension

#### Public title

Evaluation of the effect of aerobic exercise in patients with hypertension

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

They were between 50 and 70 years old. They had high blood pressure They had no history of heart or balloon surgery Not diabetic Non-athletes All subjects are in menopause

##### Exclusion criteria:

Exercise 6 months before the research Cardiovascular diseases Use of non-hypertensive drugs Unseen 3 more sessions during the investigation

#### Age

From **50 years** old to **70 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **35**

Actual sample size reached: **35**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

According to a call, people with high blood pressure who live in Abdanan will be invited to participate in the study. Then, from among the volunteers, 35 people will be purposefully selected based on the inclusion criteria. Then the names of all the subjects were written on the cards and placed in a bag. Then, the cards were taken out by lottery and the person in question was placed in the intervention and control groups, respectively. After reading the card, the card was returned to the bag.

#### 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

Sport Sciences Research Institute

#### Street address

No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.

#### City

Tehran

#### Province

Tehran

#### Postal code

1587958711

#### Approval date

2019-07-01, 1398/04/10

#### Ethics committee reference number

IR.SSRC.REC.1398.052

## Health conditions studied

### 1

#### Description of health condition studied

Women with hypertension with an age range of 50 to 70 years, according to the seventh report of the Joint National Committee for the Prevention, Diagnosis, Measurement and Treatment of Hypertension, in stage 1 hypertension (systolic pressure 159-140 and diastolic pressure 99-90 mm Mercury)

#### ICD-10 code

I10

#### ICD-10 code description

Essential (primary) hypertension

## Primary outcomes

### 1

#### Description

NT-proBNP concentration

#### Timepoint

24 hours before the start of aerobic exercise and 24 hours after 12 weeks of exercise

#### Method of measurement

ELISA kit made by the Chinese company Casabio to measure the amount of N-terminal pro - B-type natriuretic peptide (NT-proBNP)

### 2

#### Description

CT-1 concentration

#### Timepoint

24 hours before the start of aerobic exercise and 24 hours after 12 weeks of exercise

#### Method of measurement

ELISA kit made by the Chinese company Casabio to measure the amount Cardiotropin-1 ( CT-1)

### 3

#### Description

TGF-β1 concentration

#### Timepoint

24 hours before the start of aerobic exercise and 24 hours after 12 weeks of exercise

### Method of measurement

ELISA kit made by the Chinese company Casabio to measure the amount Transforming growth factor beta 1(TGF-β1)

## Secondary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

Before and after each workout

#### Method of measurement

Digital sphygmomanometer in millimeters of mercury

### 2

#### Description

Diastolic blood pressure

#### Timepoint

Before and after each workout

#### Method of measurement

Digital sphygmomanometer in millimeters of mercury

## Intervention groups

### 1

#### Description

The training program consisted of 12 weeks of aerobic exercise with an intensity of 30 to 60% of the maximum heart rate, 45 minutes per session and 3 sessions per week..

#### Category

Other

### 2

#### Description

Control group: The control group did not participate in any training program

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool Akram Clinic

##### Full name of responsible person

Somayeh Abedzadeh

##### Street address

No.10, Shahid Darabi Alley, 15 Khordad North

##### City

Abdanan

##### Province

Ilam

##### Postal code

6971753469

### Phone

+98 84 3362 4252

### Email

s.abedzade89@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Farzad Movahedi Sobhani

##### Street address

Science and Research Branch, Daneshgah Blvd,  
Simon Bulivar Blvd, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۷۷۸۹۳۸۵۵

##### Phone

+98 21 4486 5179

##### Email

f-movahedi@srbiau.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

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

Islamic Azad University

##### Full name of responsible person

Somayeh Aabedzadeh

##### Position

Phd Student

##### Latest degree

Master

##### Other areas of specialty/work

Others

##### Street address

No. 10, Shahid Darabi Alley, 15 Khordad North St

##### City

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**Province**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
Somayeh Abedzadeh  
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PHD Student  
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Master  
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## Person responsible for updating data

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**Position**  
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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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data studied can be shared after unidentified individuals.

### When the data will become available and for how long

Access information after printing results

### To whom data/document is available

Available to researchers working in academic and scientific institutions.

### Under which criteria data/document could be used

The conditions for sending documents to the applicant will be explained.

### From where data/document is obtainable

Email to the following address  
s.abedzadeh89@gmail.com

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

The applicant's request will be answered by the research team after review.

### Comments