

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The Effect of Eight Weeks of Continuous and Periodic Aerobic Exercise on some Adhesive Molecules and Inflammatory Indices in Men with Heart Failure

#### Protocol summary

##### Study aim

The spread of cardiovascular disease has an inflammatory background. The purpose is to review the changes of the adhesive molecules and inflammatory markers of men with heart failure.

##### Design

42 volunteers with heart failure aged 50-60 old years who have entered the study will be selected among the community.

##### Settings and conduct

This study is done in the form of pre-test and post-test and includes men with heart failure who have visited the Razavi Hospital in Mashhad. 48 hours before the first session and after the last training session from all subjects Blood samples will be taken in fasting mode And the steps to measure (IL-6, TNF- $\alpha$ , HS-CRP, ICAM-1, VCAM-1, E-selectin and P-selectin) will be performed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: men aged 50-60 years old, with heart failure grade 1-3; have a heart power of less than 45% and in terms of physical fitness; have potential for exercises. Exclusion criteria: having heart disease less than 5 years old; regular exercise during the past six months; performing other exercises as well.

##### Intervention groups

After screening, subjects were assigned to control, continuing aerobic exercise and periodic aerobic exercise groups. The continuous aerobic exercise program lasts for 8 weeks, 3 sessions per week that is between 30 and 50 min, with a intensity of 45-70% of the MHR that is designed using treadmill. The periodic exercise program is also designed for 8 weeks, 3 sessions per week, with a intensity of 45-80% of the MHR, which is designed using treadmill and Ergometer. Subjects will have a rest period of 5 to 10 min, depending on their circumstances. At the beginning and the end of each session, 10 minutes of stretching are performed to warm up and cool down. The

control group wont have any physical activity other than doing routine work.

##### Main outcome variables

Improve physical functioning, improve mental and social status of patients.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180721040545N1**

Registration date: **2018-08-07, 1397/05/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-07, 1397/05/16**

Update count: **0**

##### Registration date

2018-08-07, 1397/05/16

##### Registrant information

##### Name

Ladan Hosseini Abrishami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 6133

##### Email address

ladan.abrishami@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-05, 1397/05/14

##### Expected recruitment end date

2018-09-05, 1397/06/14

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Eight Weeks of Continuous and Periodic Aerobic Exercise on some Adhesive Molecules and Inflammatory Indices in Men with Heart Failure

**Public title**

The Effect of Aerobic Exercise on Patients with Heart Failure

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men aged 50-60 years old with heart failure grade 1-3 according to New York Heart Association (NYHA) criteria; have a heart power of less than 45% and in terms of physical fitness; have potential for exercises.

**Exclusion criteria:**

Having a history of heart disease less than 5 years old, having regular exercise regularly during the past six months, and performing other exercises along with the exercises during the study period, patient dissatisfaction with continued participation in the study; exacerbation of symptoms of heart failure; cardiac arrhythmias; cardiac ischemia; high blood pressure crisis; neurological problems; orthopedic problems.

**Age**From **50 years** old to **60 years** old**Gender**

Male

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **42****Randomization (investigator's opinion)**

Randomized

**Randomization description**

After screening, these subjects were randomly assigned to control group (n = 14), continuing aerobic exercise group (n = 14) and periodic aerobic exercise group (n = 14). The randomization method will be performed using the random number table. Considering the numbers from 0 to 14 for the control group, the numbers from 14 to 28 for the continuing aerobic exercise group, numbers 28 to 42 for the periodic aerobic exercise group. The researcher chooses one of the numbers and moves in the preset direction and assigns the number for the relevant 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**

Sport Sciences Research Institute of Iran

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No. 3, 5th Alley, Mir Emad Ave.

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**Postal code**

1587958711

**Approval date**

2018-06-12, 1397/03/22

**Ethics committee reference number**

IR.SSRI.REC.1397.214

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

Heart failure

**ICD-10 code**

I50

**ICD-10 code description**

Heart failure

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

Serum IL-6 level

**Timepoint**

At the beginning of the study and 8 weeks after the intervention

**Method of measurement**

Serum concentrations of IL-6 (pg/ml), Using high-sensitivity ELISA kits

**2****Description**Serum TNF- $\alpha$  level**Timepoint**

At the beginning of the study and 8 weeks after the intervention

**Method of measurement**

Serum concentrations of TNF- $\alpha$  (pg/ml), Using high-sensitivity ELISA kits

### 3

#### **Description**

Serum hs-CRP level

#### **Timepoint**

At the beginning of the study and 8 weeks after the intervention

#### **Method of measurement**

Serum concentrations of hs-CRP (ml/l), Using high-sensitivity ELISA kits

### 4

#### **Description**

Serum ICAM-1 level

#### **Timepoint**

At the beginning of the study and 8 weeks after the intervention

#### **Method of measurement**

Serum concentrations of ICAM -1 (ng/ml), Using high-sensitivity ELISA kits

### 5

#### **Description**

Serum VCAM-1 level

#### **Timepoint**

At the beginning of the study and 8 weeks after the intervention

#### **Method of measurement**

Serum concentrations of VCAM -1 (ng/ml), Using high-sensitivity ELISA kits

### 6

#### **Description**

Serum E-selectin level

#### **Timepoint**

At the beginning of the study and 8 weeks after the intervention

#### **Method of measurement**

Serum concentrations of E-selectin (ng/ml), Using high-sensitivity ELISA kits

### 7

#### **Description**

Serum P-selectin level

#### **Timepoint**

At the beginning of the study and 8 weeks after the intervention

#### **Method of measurement**

Serum concentrations of P-selectin (ng/ml), Using high-sensitivity ELISA kits

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group1: This group carries out continuous aerobic exercise. Continuous aerobic exercise program (with intensity of 45-70% of maximum heart rate) for 8 weeks (3 sessions per week and 30-50 minutes each session) will be performed, which is designed using treadmill. At the beginning of each session, 10 min of stretching exercise were performed to warm up, and during the training the subjects were monitored. The intensity of exercise is controlled and recorded using heart rate and ECG then at the end of the training, the subjects will cool down using stretching exercises.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group 2: In this group, the Periodic aerobic exercise program (with three sessions per week, and a intensity of 45-80% of the maximum heart rate) will be design using treadmill and wheelchair. Subjects have resting period between 5-10 minutes according to individual circumstances. At the beginning of each session, 10 min of stretching exercise were performed to warm up, and during the training the subjects were monitored. The intensity of exercise is controlled and recorded using heart rate and ECG then at the end of the training, the subjects will cool down using stretching exercises.

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: The control group will not have any physical activity other than doing routine work.

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Razavi Hospital

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

Reza Saeedi

##### **Street address**

Razavi Hospital, After Qaem Bridge, Azadi Highway, Mashhad, Khorasan Razavi Province, IRAN

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Islamic Azad University, Neyshabour Branch  
**Full name of responsible person**  
Mohammad Hussein Hemmati  
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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, Neyshabour Branch  
**Proportion provided by this source**  
100

**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
empty

**Country of origin**  
**Type of organization providing the funding**  
Other

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Islamic Azad University, Neyshabour Branch  
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Ladan Hosseini Abrishami  
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**Latest degree**  
Ph.D.  
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Physiology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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

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

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

Data related to the indices (IL-6, TNF- $\alpha$ , hs-CRP, ICAM-1, VCAM-1, E-selectin, P-selectin) will be shared.

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

From 2019

### To whom data/document is available

Academic researchers

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

Use with reference

### From where data/document is obtainable

ladan.abrishami@gmail.com

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

Maximum one week

### Comments