

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- α , 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.

AgeFrom **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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Province

Tehran

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- α level**Timepoint**

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

Method of measurementSerum concentrations of TNF- α (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
Full name of responsible person
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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- α , 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