Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 8weeks, 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 Hosseni 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
Street address
No. 3, 5th Alley, Mir Emad Ave.
City
Tehran
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 measurement
Serum 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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Province
Razavi Khorasan
Postal code
9198613636
Phone
+98 51 3666 8888

Email
info@razavihospital.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University, Neyshabour Branch
Full name of responsible person
Mohammad Hussein Hemmati
Street address
Pajohesh Ave., Islamic Azad university complex.
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Phone
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Neyshabur@iau-neyshabur.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, 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
Ladan Hosseni Abrishami
Position
.Ph.D student
Latest degree
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Other areas of specialty/work
Physiology
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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-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