Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of concurrent aerobic- resistance training on aerobic power, heart structure and function, heart rate variables, galectin-3 and N-terminal pro-brain natriuretic peptide in patients with chronic heart failure

Protocol summary

Study aim

the effect of a period of aerobic exercise on aerobic power, heart structure and function, heart rate variables, galectin-3 and NT proBNP in patients chronic heart failure With grade II-III NYHA classification.

Design

A clinical trial with a control group, 40 patients are selected in two groups of simple randomized in patients with Class II-III New York Heart Association(NYHA) of classification of heart failure with EF> 20%.

Settings and conduct

The present research is a semi-experimental study on patients with heart failure hospitalized in Hashamat Hospital in Rasht and referring to the specialized clinic of this hospital, after the introduction of cardiologists will participate in exercise training three days a week for 8 weeks.6-minute walk test, blood sampling and echocardiography is performed before and after eight weeks of training.

Participants/Inclusion and exclusion criteria

40 patients are included with a range of 52 to 78 years of age, II-III cardiac failure with a ejection fraction of more than 20% in the study. Patients are not included with psychiatric and nervous disorders treated with tranquilizers, orthopedic, speaking and hearing problems in the study.

Intervention groups

The control group receives the usual treatment and care that the hospital has in its work schedule. The experimental group, in addition to the usual treatment, performs regular exercises, including: eight weeks, three times a week for 60 to 90 minutes a day, progressive aerobic exercises with 60-90% of maximum heart rate, resistance training with intensity 70-50% one maximal repeat, walking 4 sessions per week with average intensity 70 -50% maximum resting heart rate

Main outcome variables

aerobic power, heart structure and functional, heart rate variables, galectin-3 and N-terminal pro-brain natriuretic peptide(NT Pro-BNP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150531022498N24**
Registration date: **2018-07-25, 1397/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**
Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

Name

Ramin Shabani

Name of organization / entity

Islamic Azad University

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of concurrent aerobic- resistance training on aerobic power, heart structure and function, heart rate variables, galectin-3 and N-terminal pro-brain natriuretic peptide in patients with chronic heart failure

Public title

The effect of exercise training on chronic heart failure patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic heart failure in NYHA II-III Classification with ejection fraction(EF) > 20%

Exclusion criteria:

Patients with NYHA IV class Patients with acute myocarditis Patients with disorder exercise (such as severe aortic stenosis, severe hypertrophic cardiomyopathy (HOCM), etc.) Patients are not able to perform 6MWT ''. For example, osteoarthritis, knee surgery, cerebrovascular infarct , and so on Patients with specific cognitive impairment Patients with psychiatric and nervous disorders who are being treated with sedative medicines Patients with orthopedic, verbal and auditory problems

Age

From **52 years** old to **78 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random, Among the candidates who are qualified, the lottery method is performed after a justification session and expressing the possible benefits and disadvantages

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

Ethics Committee of Islamic Azad University Rasht Branch

Street address

Islamic Azad University Rasht Branch, Taleshan Bridge, Rasht

City

Rasht

Province

Guilan

Postal code

4147654919

Approval date

2018-02-10, 1396/11/21

Ethics committee reference number

IR.IAU.RASHT.REC.1396.101

Health conditions studied

1

Description of health condition studied

Chronic Heart Failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart failure, Congestive heart disease Right ventricular failure (secondary to left heart failure)

Primary outcomes

1

Description

galectin-3

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Serum level by ELISA method(n mol/ ml)

2

Description

N-terminal pro-brain natriuretic peptide

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Serum level by ELISA method(n mol/ ml)

3

Description

Aerobic Power

Timepoint

Before the intervention and 8 weeks after the

intervention

Method of measurement

Maximum heart rate, 6-Minute Walk Test(6MWT)

4

Description

Structure and function of heart

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Echocardiography

5

Description

Heart rate variables

Timepoint

Before the intervention and 8 weeks after the intervention

Method of measurement

Maximum heart rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Aerobic training and concurrent resistance for eight weeks and three days a week, 60 minutes a day that progressive aerobic exercise with 60 to 90 percent of maximum heart rate at rest and strength by 60 to 85% of one repetition maximum

Category

Prevention

2

Description

Control group: Without intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Heshmat Hospital

Full name of responsible person

Zahra Mahmoodi

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15 Khordad Avenue , Dr Heshmat Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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

zahra mahmoodi

Position

PHD Student

Latest degree

Master

Other areas of specialty/work

Exercise Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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