

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The study of effect of 8 weeks of exercise training on The most common aggravating factors of heart failure patients

Protocol summary

Summary

The purpose of this study is to reduce aggravating factors of heart failure with exercise training. patients are randomly selected. A clinical trial study of the most important aggravating factors, MI, renal, pulmonary, diabetes and hypertension was determined. 38 Patients of Heart Failure with grade II-III ,in the age range of 40-70 years are divided into intervention and control groups. The patients develops symptoms of heart failure, arrhythmia, ischemia and HTN crisis, they are excluded from the study. And patients with neurological, orthopedic, speech and hearing problems are not included in the study. In the intervention group, a 8-week of training program is performed to Pre-exercise with warm-up, and cool down post-exercise for 5 to 10 minutes. Twice a week treadmill with an intensity of 70-60% maximum heart rate in 20 minutes, Arm ergometer for 3 minutes in the first week and 6 minutes in the last week, Incentive spirometry 10 minutes for 3 days a week, 30 minute walking exercises, Weighing for 30 minutes and 10-15 times at the start of week with 30-40% 1RM for hand weights and 50-60% 1RM for foot weights in two sets with 5 minutes rest between the two sets, red resistance band in the first two weeks with 10-8 repeats, green color for the third to fifth week with 12-10 repeats, and blue color from 6 to 8 weeks with 15-12 repeats and 5 minutes of rest between the two sets. Measurment tools are ECG, pulseoxymeter, echocardiography, CXR, 6-minute test, Peak Flowmeter, Spirometry, Blood test before and after exercise.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070534911N1**

Registration date: **2017-07-18, 1396/04/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-18, 1396/04/27

Registrant information

Name

Zahra Mahmoodi

Name of organization / entity

Heshmat Hospital/Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 9064

Email address

gicrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of effect of 8 weeks of exercise training on The most common aggravating factors of heart failure patients

Public title

The effect of exercise exercises on heart failure patient

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: The age range 40-70 years; with II, III grade heart failure ; patient with the most important aggravating factors including kidney, lung, diabetes and hypertension difficulties Exclusion criteria: :Exacerbation of heart failure symptoms; arrhythmia ; ischemic ; HTN crisis; Psychiatric problem; orthopedic problem; speech problem; hearing problem

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description

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 Guilan University of Medical Sciences

Street address

Shahid Beheshti freeway

City

Rasht

Postal code

4193893345

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.GUMS.REC.1396.107

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.0

ICD-10 code description

Congestive heart disease

Primary outcomes

1

Description

Lung volume In the intervention group

Timepoint

Before and after 8 weeks of exercise training

Method of measurement

spirometry

2

Description

Lung Volume In the control group

Timepoint

Before and 8 weeks After the start of the study

Method of measurement

Spirometry

3

Description

Lung capacity In the intervention group

Timepoint

Before and 8 weeks after exercise training

Method of measurement

spirometry

4

Description

Function and structure of the heart include: LVEF left ventricular fraction (%), systolic ending volume (ESV) and diastolic end volume (EDV)

Timepoint

before and after 8 weeks of exercise training

Method of measurement

Echocardiography

5

Description

Heart Rate

Timepoint

before and after of 8 week

Method of measurement

Pulseoximeter

6

Description

Blood Pressure

Timepoint

before and after of 8 weeks of exercise training

Method of measurement

pressure indicator

7

Description

cr(Creatine Blood)

Timepoint

before and after 8 weeks of exercise training

Method of measurement

Blood Test

8

Description

potency function

Timepoint

before and after 8 weeks of exercise training

Method of measurement

6-minute test

9

Description

HDL, LDL

Timepoint

before and after 8 weeks of exercise training

Method of measurement

Blood test

10

Description

BS₉, HbA1C

Timepoint

before and after 8 weeks of exercise training

Method of measurement

Blood Test

11

Description

Lung capacity In the controlgroup

Timepoint

before and 8 week After the start of the study

Method of measurement

Spirometry

12

Description

Blood Pressure in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

pressure indicator

13

Description

Cr(cratinine Blood) in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

Blood Test

14

Description

Heart rate in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

pulseoximetry

15

Description

potency function in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

6 minute test

16

Description

HDL, LDL Blood in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

Blood Test

17

Description

HbA1C, BS in the control group

Timepoint

before and 8 week After the start of the study

Method of measurement

Blood Test

18

Description

Function and structure of the heart include: LVEF left ventricular fraction (%), systolic ending volume (ESV) and diastolic end volume (EDV) in the control group

Timepoint

Before and 8 weeks After the start of the study

Method of measurement

EchoCardiography

Secondary outcomes

1

Description

Cardiac arrhythmia

Timepoint

During the exercise

Method of measurement

manitoring

2

Description

Ischemia

Timepoint

During the exercise
Method of measurement
manitoring

3

Description

HTN crisis

Timepoint

By indication symptoms

Method of measurement

pressure indicator

Intervention groups

1

Description

Intervention group: How to exercise sports interventions
In the test group, that is For 8 weeks, 2 times a week for 30 minutes of treadmill, Then, the Arm ergometer first started for 3 minutes and up to 8 weeks to 6 minutes, then 10 minutes of incentive spirometry will be done. In addition, 3 times a week for a 30 minute walking, Then, for 30 minutes, the weight of the hand and foot should be repeated 10-15 times in two sets with 5 minutes of rest between the two sets, After that, for 30 minutes, the theraband (elastic band) is performed at the beginning of low resistance and then with medium resistance. In the exercise with weight and theraband, changes in any organ or repeat exercises, rest was considered for 2 minutes. Before and after the exercises, they will be warmed and cooled for 10-5 minutes.

Category

Rehabilitation

2

Description

Control group: There is no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmate Hospital

Full name of responsible person

Zahra Mahmoodi

Street address

15 Khordad Street- Heshmat Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Guilan University of Medical Sciences

Full name of responsible person

Shademan Nehmati

Street address

Shahid Beheshti freeway

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan Guilan University of Medical Sciences

Full name of responsible person

Zahra Mahmoodi

Position

Ph.D Student in Sports Physiology / Nurse of responsible for patient education

Other areas of specialty/work

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Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Zahra Mahmoodi

Position

Ph.D Student in Sports Physiology / Nurse of responsible for patient education

Other areas of specialty/work**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty