

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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**

BS<sub>9</sub>, 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  
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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  
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**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*