

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of a Cardiac Rehabilitation Course on Left ventricular Function and Hemodynamic Heart factors in Patients with Congestive Heart Failure

Protocol summary

Study aim

Determining the effect of a course of cardiac rehabilitation exercises on left ventricular function, right ventricular function, positive DP / DT, negative DP / DT, blood pressure (BP), heart rate (HRV), maximal cardiorespiratory capacity, hemodynamic pressure ratio Maximum, the ratio of submaximal pressure to the maximum in CHF patients

Design

Clinical trial with control group, non-random.

Settings and conduct

Patients who have been referred to the cardiac rehabilitation department of Heshmatieh Hospital. At each session, take a 10-minute walk to warm up, followed by a 20-minute period of breathing exercises and non-resistance movements of the limbs, and about 40 to 50 minutes of training in 40 to 70 percent of their maximum oxygen consumption, which includes exercises. Exercise with an ergometer bike for 20 minutes, an arm ergometer for 10 minutes and a treadmill for 20 minutes.

Participants/Inclusion and exclusion criteria

Patients with heart disorders, including coronary artery disease and various types of cardiomyopathy with a ejection fraction of 30 to 50 percent, are eligible for admission. And the conditions for not entering the study are patients with low physical ability and non-cardiac disorders and ejection fraction more than 55%.

Intervention groups

There are 40 patients in the study, 20 in the control group who do not receive any rehabilitation program, and 20 in the intervention group. In intervention group that participates in a heart failure management program for 8 weeks 3 sessions each week in a rehabilitation program. The patient's training program, which includes an aerobic exercise program and each session includes an hour and a half of aerobic exercise, will be monitored.

Main outcome variables

Increased oxygen consumption of the patient as well as

improvement in cardiac output fraction

General information

Reason for update

Acronym

CVR

IRCT registration information

IRCT registration number: **IRCT20200418047118N1**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **prospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

akbar pejhan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 8401 8443

Email address

pejhana@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a Cardiac Rehabilitation Course on Left ventricular Function and Hemodynamic Heart factors in Patients with Congestive Heart Failure

Public title

Evaluation of the effect of rehabilitation in heart patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with heart disorders, such as impaired bowel function Decreased cardiac output Increased intracardiac pressure function Disabling symptoms such as fatigue, pain, peripheral edema Decreased respiratory function Progressive hormonal and endothelial nerve disorders Sports intolerance Weak prognosis Low quality of life Age between 40 and 80 years

Exclusion criteria:

History of stroke Extensive damage to the anterior myocardial area Reconstructive vascular or regenerative angina procedures in the last 3 months Orthopedic disorder Alcohol or drug use Patients with pacemakers or defibrillators Flutter and atrial fibrillation Insulin-dependent diabetes mellitus Chronic obstructive pulmonary disease Severe renal impairment Non-cardiac comorbidities

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not 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

Sabzevar University of Medical Sciences Ethics Committee

Street address

Cardiac Rehabilitation Department, second floor, Heshmatieh Hospital, next to the central headquarters, Asadabadi Street, Sabzevar. IRAN

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.MEDSAB.REC.1399.032

Health conditions studied**1****Description of health condition studied**

congestive heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes**1****Description**

The number of people whose ejection fraction are more than 30 percent and less than 50 percent

Timepoint

Measure the heart ejection fraction before the start of the study and at the end of the study after 24 practice sessions

Method of measurement

Two-dimensional echocardiography machine

2**Description**

recovery rate in cardiac function factors

Timepoint

Before and after the study, during the rehabilitation period and during training

Method of measurement

Using a mercury pressure-gauge , pulse oximeter

3**Description**

Maximum and minimum hemodynamic pressure rate

Timepoint

At the end of the cardiac rehabilitation period

Method of measurement

By related formulas and equations

Secondary outcomes

1

Description

Maximum heart capacity (vo2)

Timepoint

During rehabilitation exercises

Method of measurement

By sports test and specialized equation test

Intervention groups

1

Description

Intervention group: It consists of 20 patients who, with full awareness and satisfaction for two months, will take part in three regular sessions of cardio rehabilitation training each week. Patients have specific exercises with different devices such as: 1- Ergoline treadmill made in Germany. 2. Ergoline bicycle made in Germany. 3- Ergoline handmade bicycles made in Germany. Also, the patient's blood pressure will be measured by a manometer and heart rate monitor, and the amount of oxygen in the blood will be measured by the pulse oximeter, Beurer cardiofrequency tester before, after, and during exercise.

Category

Rehabilitation

2

Description

Control group: Includes 20 patients who are physically similar to the experimental group who do not participate in cardiac rehabilitation exercises and they will be asked to only participate in the initial and final exams and evaluations of this course with full satisfaction and awareness, as well as the patients of the experimental group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatieh hospital

Full name of responsible person

Hamid Marefati

Street address

Asadabadi St., next to the Central Headquarters,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshte Ghorat

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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

Sabzevar University of Medical Sciences

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

Sabzevar University of Medical Sciences

Full name of responsible person

Akbar Pejhan

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

clinical results report

When the data will become available and for how long

All researchers can use these clinical data for all time without any limitation after publication of data in scientific journals.

To whom data/document is available

All researchers can use these clinical data for all time after publication in journal.

Under which criteria data/document could be used

The publication of the results in the article is for public information and there is no special condition.

From where data/document is obtainable

Dr. Hamid Marefati

What processes are involved for a request to access

data/document

He/she can send an e-mail to corresponding author of paper.

Comments

There is no specific explanation.