Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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, Heshmatieh Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
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Fereshte Ghorat
Street address
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Web page address
http://medsab.ac.ir/index.aspx?pageid=6323&p=1
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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Full name of responsible person
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Associate Professor

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Person responsible for updating data

Contact

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Full name of responsible person
Akbar Pejhan

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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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.