

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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)

##### Phone

+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,  
Heshmatieh Hospital

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

#### Phone

+98 51 4401 1600

#### Fax

+98 51 4423 8719

#### Email

H.marefati@yahoo.com

#### Web page address

<http://www.medsab.ac.ir/index.aspx?siteid=1&pageid=6323>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Fereshte Ghorat

##### Street address

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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

##### Phone

+98 51 4444 6070

##### Email

etebari1404@gmail.com

##### 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

**Street address**

Sabzevar University of Medical Sciences Campus  
Complex; Above the tombs of the unknown martyrs;  
Tohidshahr Boulevard

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9617213112

**Phone**

+98 51 4401 8443

**Fax**

+98 51 4401 8424

**Email**

pejhana@medsab.ac.ir

**Web page address**

<http://www.medsab.ac.ir/>

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Hamid Marefati

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

**Street address**

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

**City**

Sabzevar

**Province**

Razavi Khorasan

**Postal code**

9613873136

**Phone**

+98 51 4401 1663

**Fax**

+98 51 4423 8719

**Email**

H.marefati@yahoo.com

**Web page address**

<https://heshmatie.medsab.ac.ir/index.aspx?siteid=4&fkeyid=&siteid=3&pageid=6323>

**Person responsible for updating data**

**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**

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+98 51 4401 8424

**Email**

pejhana@medsab.ac.ir

**Web page address**

<http://www.medsab.ac.ir/>

**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.