

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Protocol summary

Study aim

Comparison of Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Design

The clinical trial has a control group, is single-blind, randomly selected with a concealed envelope, and is on 36 patients with chronic heart failure.

Settings and conduct

The study location is Emam Reza Educational, Research, and Treatment Center in Mashhad. Patients and physicians have been blinded. Informed consent, a six-minute walk test, blood pressure measurement, an ECG Holter monitor, a lipid profile test, and TNF alpha are taken from all samples.

Participants/Inclusion and exclusion criteria

Among the patients with chronic heart failure referred to Emam Reza Educational, Research, and Treatment Center in the age range of 50 to 70 years and with an ejection fraction of less than 50%, they are selected by the available sampling method.

Intervention groups

There are three groups in this study. Using a concealed envelope, the samples are simply randomly assigned to one of three groups. Group 1: Individuals only receive standard medication treatment. Group 2: Individuals In addition to standard medication treatment, perform routine breathing exercises. Group 3: Individuals In addition to standard medication treatment, perform gradual, slow breathing exercises guided by a respirometer Biofeedback.

Main outcome variables

Basic respiration rate; Inflammation; Heart Rate Variability

General information

Reason for update

increasing the sample size The description of the control group was modified, where subjects received only standard drug treatment. recording the completion of the sample Recording the date of the end of the study Changing the status of the responsible person

Acronym

IRCT registration information

IRCT registration number: **IRCT20210426051093N1**
Registration date: **2021-12-04, 1400/09/13**
Registration timing: **prospective**

Last update: **2023-11-04, 1402/08/13**

Update count: **1**

Registration date

2021-12-04, 1400/09/13

Registrant information

Name

Mahdi Rahmati-Yami

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 51 3760 5302

Email address

mahdi.rahmati@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

2022-01-08, 1400/10/18

Actual recruitment end date

2023-02-13, 1401/11/24

Trial completion date

2023-03-13, 1401/12/22

Scientific title

Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Public title

Comparison of The Routine Respiratory and Gradual Device-guided Slow Breathing Exercises on Inflammation and Heart Rate Variability in Patients With Heart Failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Class II and III heart failure based on NYHA criteria
Having suffered from heart failure for the past 3-5 years
Clinical status and stable hemodynamics at least one month before entering the study
Ejection fraction less than 50% based on echocardiography
Being treated with standard medication
Age range: 50 to 70 years

Exclusion criteria:

Unstable angina and complex ventricular arrhythmias
The occurrence of myocardial infarction in the past year having pacemaker
During the last six months, have bypass surgery or angioplasty.
Participate in other exercise programs six months before the start of the study.
The existence of musculoskeletal disorders that prevent normal walking
Existence of cognitive disorders
Lack of personal desire to cooperate
History of lung disease, smoking, angina, heart attack or heart surgery (less than six months), orthopedic or neurological diseases, steroid therapy, or chemotherapy

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly assigned to one of the groups by a researcher using a Concealed envelope method.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is a one-way blinded controlled clinical trial, and the cardiologist and patients are not aware of being in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Design and construction of a respirometer biofeedback device for respiratory training of the subjects

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tarbiat Modares University Ethics Committee

Street address

Tehran Jalal AleAhmad Nasr

City

Tehran

Province

Tehran

Postal code

14115111

Approval date

2021-10-23, 1400/08/01

Ethics committee reference number

IR.MODARES.REC.1400.200

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

Chronic heart Failure

ICD-10 code

I50

ICD-10 code description

Heart failure

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

The basic rate of respiration

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Average rate of five minutes of respiration based on respirometer biofeedback.

2**Description**

Inflammation

Timepoint

48 hours before the intervention and 48 hours after the

end of four weeks of intervention

Method of measurement

According to the report of TNF-alpha in an enzyme-linked immunosorbent assay device

3

Description

Heart Rate Variability

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Holter monitoring device

Secondary outcomes

1

Description

Quality of Life

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Minnesota Quality of Life Questionnaire Score

2

Description

Cholesterol

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Based on an autoanalyzer device's report from a person's blood serum

3

Description

Triglyceride

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

4

Description

High-Density Lipoprotein (HDL)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

5

Description

Low-Density Lipoprotein (LDL)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

From a person's blood serum based on the report of an autoanalyzer device

6

Description

Systolic blood pressure at rest

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the average Holter blood pressure report

7

Description

Diastolic blood pressure at rest

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the average Holter blood pressure report

8

Description

Rate of perceived exertion

Timepoint

48 hours before and after the six-minute walk test and 48 hours after the end of four weeks of intervention before and after the six-minute walk test

Method of measurement

Based on the Borg scale

9

Description

Standard Deviation of NN Intervals (SDNN)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

10

Description

Root Mean Square of Successive Differences between normal heartbeats (RMSSD)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

11

Description

The Percentage of adjacent NN intervals that differ from each other by more than 50 ms (pNN50)

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

According to the report of the cardiac Holter device

12**Description**

Physical Functional Performance

Timepoint

48 hours before the intervention and 48 hours after the end of four weeks of intervention

Method of measurement

Based on the 6-Minute Walk Test (6MWT)

Intervention groups**1****Description**

Control group: Individuals only receive standard medication treatment.

Category

Treatment - Drugs

2**Description**

Intervention group; in the second group, or Routine Breathing Exercises group, for four weeks, in the first week for 20 minutes, and with an increase of 3.5 minutes at the beginning of the second, third, and fourth weeks, in the fourth week for 30 minutes, the person does these exercises. The patient is asked to lean back in the chair and sit in a comfortable chair. The patient then holds an incentive spirometry in his hand and, after a normal exhalation, places the spirometry mouthpiece in his or her mouth and performs inhalation slowly and deeply as much as possible. The patient performs this operation three times at the beginning of each week, and its average is recorded as the maximum respiratory capacity. The patient is then asked to perform a deep breathing exercise with 60% of the base volume obtained. This exercise is given twice a day, 10 times each time, with 30 to 60 seconds of rest between each exercise. At the beginning of each week, two exercises will be added to the exercises, so that at the end of the fourth week, this exercise will be performed 16 times.

Category

Rehabilitation

3**Description**

Intervention group, In the third group, or Gradual Device-guided Slow Breathing Exercises, for four weeks, in the first week for 20 minutes, and with an increase of 3.5 minutes at the beginning of the second, third, and fourth weeks, in the fourth week for 30 minutes. Under the guidance of Respirometer Biofeedback, observing the

overload principle, a total reduction of 50% of the respiratory rate is applied, which in four stages is 12.5% compared to the basic respiratory rate, which is measured at the beginning of each week. The basal rate of respiration and the rate of decrease in the rate of respiration relative to the basal rate obtained at the beginning of each week are recorded and reported for each individual.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Educational, Research, and Treatment Center

Full name of responsible person

Farveh Vakilian

Street address

Emam Reza Educational, Research, and Treatment Center, Imam Reza Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3854 3031

Fax

+98 51 3859 1057

Email

IRH@mums.ac.ir

Web page address

<https://emamreza.mums.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Farhad Daneshjoo

Street address

Nasr, Jalal AleAhmad, Tehran

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 2005

Email

pres@modares.ac.ir

Web page address

<https://www.modares.ac.ir>

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
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
Tarbiat Modares University
Full name of responsible person
Roya ravanbod
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physical therapy
Street address
Nasr, Jalal AleAhmad, Tehran
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 4510
Email
ravanbod@modares.ac.ir
Web page address
https://www.modares.ac.ir/pro/academic_staff/ravanbod

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Roya ravanbod
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physical therapy

Street address
Nasr, Jalal AleAhmad, Tehran
City
Tehran
Province
Tehran
Postal code
1411713116
Phone
+98 21 8288 4510
Email
ravanbod@modares.ac.ir
Web page address
https://www.modares.ac.ir/pro/academic_staff/ravanbod

Person responsible for updating data

Contact

Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Mahdi Rahmati-Yami
Position
PhD Candidate
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Unit 4, Floor 2, NO 1, Fadjr 11 Alley, Sahedi 5 St.,
Sajedi Blvd., Mashhad, Razavi Khorasan Province, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9197847442
Phone
+98 51 3760 5302
Fax
Email
mahdi.rahmati@modares.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data

When the data will become available and for how long

8 months after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

For medical and research purposes

From where data/document is obtainable

Roya Ravanbod Tarbiat Modares University

ravanbod@modares.ac.ir

https://www.modares.ac.ir/pro/academic_staff/ravanbod

What processes are involved for a request to access data/document

Approval of supervisors

Comments