

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparing the effect of acupuncture and medication on cardiac and autonomic function in patients with heart failure

Protocol summary

Study aim

The purpose of this study is comparing the effect of adding acupuncture to medication with medication alone on cardiac and autonomic function in patients with heart failure.

Design

clinical trial with intervention and control group, single blind randomized trial with fleiss table, each group contain 36 member

Settings and conduct

heart failure clinic of Imam Reza Hospital, Mashhad 72 patients with class II and III heart failure and ejection fraction less than 40% will be entered into this study and will randomly be divided into two groups of intervention (acupuncture and medication) and control (medication alone). In the intervention group, acupuncture will be performed three times a week. The cardiologist and statistician will be blind to the assigned groups. The acupuncturist and patients will not be blind to the type of treatment.

Participants/Inclusion and exclusion criteria

Patients older than 21 years of age with stable and compensated heart failure, class 2 and 3, and left ventricular ejection fraction less than or equal to 40% will be included.

Intervention groups

Two groups of intervention (acupuncture and medication) and control (medication alone)

Main outcome variables

electrocardiography, echocardiography, 6-minute walk test, heart rate and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201706087265N8**

Registration date: **2017-09-22, 1396/06/31**

Registration timing: **prospective**

Last update: **2019-07-01, 1398/04/10**

Update count: **1**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of acupuncture and medication on cardiac and autonomic function in patients with heart failure

Public title

Effect of acupuncture on cardiac function and autonomic nervous system in heart failure patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age \geq 21 Heart failure with reduced ejection fraction (LVEF \leq 40%) New York Heart Association class II-III sinus rhythm patient consent

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomized into intervention group (real acupuncture + medication) and control group (medication) by random allocation with Fleiss table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study patients were not blind. the cardiologist was blind about study groups but it was not possible about acupuncturist. the questioner was not blind but the analyzer was blind.

Placebo

Not used

Assignment

Parallel

Other design features

The list of random numbers will be provided for the two groups using the Fleiss table.

Secondary Ids

empty

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Qorashi building, Daneshgah street

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Province

Razavi Khorasan

Postal code

9177948564

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.MUMS.REC.1394.214

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

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

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

Blood pressure

Timepoint

before study and at week 8

Method of measurement

Using sphygmomanometer

2**Description**

Heart Rate

Timepoint

before study and at week 8

Method of measurement

Examination of pulse and counting the pulses per minute

3**Description**

6 minute walk test

Timepoint

before study and at week 8

Method of measurement

Measuring the patient's walking distance on a specified path within 6 minutes.

4**Description**

PR wave

Timepoint

before study and at week 8

Method of measurement

Time distance of PR wave in electrocardiogram (seconds)

5**Description**

QRS wave

Timepoint

before study and at week 8

Method of measurement

Time distance of QRS wave in electrocardiogram (seconds)

6

Description

Ejection Fraction

Timepoint

before study and at week 8

Method of measurement

Percentage of cardiac ejection fraction in echocardiography

7

Description

Righ ventricular end diastolic diameter

Timepoint

before study and at week 8

Method of measurement

Righ ventricular end diastolic diameter in echocardiography (cm)

8

Description

left ventricular end diastolic diameter

Timepoint

before study and at week 8

Method of measurement

left ventricular end diastolic diameter in echocardiography (cm)

9

Description

Tricuspid annular plane systolic excursion

Timepoint

Before study and at week 8

Method of measurement

Measuring by echocardiography (mm)

10

Description

End Systolic Volume

Timepoint

before study and at week 8

Method of measurement

End Systolic Volume in echocardiography (ml)

11

Description

NYHA class

Timepoint

before study and at week 8

Method of measurement

The amount of activity that dyspnea occurs according to the patient's history (a 4 points scale)

Secondary outcomes

1

Description

Quality of life

Timepoint

before study and at week 8

Method of measurement

The score of patient's quality of life according to SF36 questionnaire

Intervention groups

1

Description

Intervention group: 12 sessions of acupuncture (3 times per week) and medication

Category

Treatment - Other

2

Description

Control group: medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiology clinic, Imam Reza Hospital

Full name of responsible person

Dr. Farveh Vakilian

Street address

Cardiology clinic, Imam Reza Hospital, Ibn Sina street, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

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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

Vice Chancellor for research of Mashhad 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**

Department of Cardiology, School of Medicine, Mashhad University of Medical Sciences

Full name of responsible person

Dr. Farveh Vakilian

Position

Associate Professor/Cardiologist

Latest degree

Specialist

Other areas of specialty/work**Street address**

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Full name of responsible person

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Latest degree

Ph.D.

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Latest degree

Medical doctor

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Fnsb9190@gmail.com

Web page address**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

No more data is available.

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

No - There is not 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