# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 groupncontain 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

**Country**
Iran (Islamic Republic of)

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+98 51 1855 2188

**Email address**
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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>= 21 Heart failure with reduced ejection fraction (LVEF ≤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
**City**
Mashhad
**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 occures 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**
Dr Mohsen Tafaghodi
**Street address**

University Central building, Daneshgah street

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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**

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## Person responsible for scientific inquiries

**Contact**

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Department of Chinese and Complementary Medicine, School of Traditional and Complementary Medicine,

**Full name of responsible person**

Dr. Hoda Azizi

**Position**

Clinical PhD, Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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School of Traditional and Complementary Medicine, university campus, Azadi square

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## Person responsible for updating data

**Contact**

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School of Medicine, Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Farzaneh Norouzi

**Position**

Medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

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