Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of acupuncture and cardiac rehabilitation on patients after percutaneous coronary intervention in comparison to cardiac rehabilitation alone

Protocol summary

Study aim

The aim of this study is to assess the possible improvements in the symptoms of patients with percutaneous coronary intervention after cardiac rehabilitation combined with acupuncture in comparison with cardiac rehabilitation alone, on blood pressure (systolic and diastolic) and heart pulse rate.

Design

The study population consisted of 50 patients with a history of (PCI) who are referred to Shaheed Faghihi hospital in Shiraz and will be randomly divided into two groups: A and B (25 People in each group). Demographic characteristics of both groups in terms of age and sex are similar. To randomize the study, a randomized block method is used.

Settings and conduct

This is a randomized clinical trial that will be conducted on referrals to physicians and rehabilitation clinics of Shaheed Faghihi Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: completing informed consent; patients with cardiac diseases 6 weeks to 3 months after stent insertion. Exclusion criteria: diabetes with uncontrolled blood sugar; rheumatic diseases and collagen and vascular disease; bleeding disorder; inability to communicate and complete questionnaires; history of significant liver and kidney disorders; systolic blood pressure ≥ 200 mm Hg or diastolic blood pressure ≥ 110 mm Hg; uncontrolled arrhythmia; uncontrolled congestive heart failure and acute pericarditis or myocarditis.

Intervention groups

Treatment in group A includes acupuncture interventions on area related to heart meridian for 30 minutes and 10 courses before starting the cardiac rehabilitation process. Group B treatment includes only cardiac rehabilitation process for 10 courses.

Main outcome variables

More possible improvements in the cardiac function of patients with percutaneous coronary intervention after cardiac rehabilitation combined with acupuncture in comparison with cardiac rehabilitation alone.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140126016372N3**
Registration date: **2019-02-02, 1397/11/13**
Registration timing: **retrospective**

Last update: **2019-02-02, 1397/11/13**
Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name
Farzad Nikaein
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-01, 1397/05/10

Expected recruitment end date

2018-10-01, 1397/07/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of acupuncture and cardiac rehabilitation on patients after percutaneous coronary intervention in comparison to cardiac rehabilitation alone

Public title
Investigating the effect of acupuncture and cardiac rehabilitation on patients after percutaneous coronary intervention

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Completing informed consent Patients with cardiac diseases 6 weeks to 3 months after stent insertion

Exclusion criteria:
Diabetes with uncontrolled blood sugar, rheumatic diseases and collagen and vascular disease Bleeding disorder, inability to communicate and complete questionnaires History of significant liver and kidney disorders Systolic blood pressure ≥ 200 mm Hg. Diastolic blood pressure ≥ 110 mm Hg. Uncontrolled Arrhythmia, Uncontrolled congestive heart failure, Acute pericarditis or myocarditis

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In the randomization process, the envelopes containing letters A and B are used so that the letters inside the envelopes are not recognizable from the outside, as well as the manner in which the envelopes are placed randomly in succession and the person present at the time The randomization of content and the ordering of information in envelopes is not known.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and investigators do not know which patient is in the treatment group and only the patients are known under the names of groups A and B.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, opposite Palestine Street, Zand Ave., Shiraz

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2018-07-24, 1397/05/02

Ethics committee reference number
IR.SUMS.MED.REC.1397.135

Health conditions studied

1

Description of health condition studied
Ischemic heart diseases

ICD-10 code
Z98.61

ICD-10 code description
Coronary angioplasty status

Primary outcomes

1

Description
Blood Pressure (systolic and diastolic)

Timepoint
In both groups before and after each course of cardiac rehabilitation with or without acupuncture for 10 courses.

Method of measurement
Beurer upper arm digital blood pressure monitor

2

Description
Heart pulse rate

Timepoint
In both groups before and after each course of cardiac rehabilitation with or without acupuncture for 10 courses.

Method of measurement
Beurer digital pulse rate monitor device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before starting the cardiac rehabilitation process, acupuncture intervention will be done on area related to heart meridian with needle vertically (CUN 0.3 -1) for 30 minutes and 10 courses.
Category
Rehabilitation

2

Description
Control group: Only cardiac rehabilitation process.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shaheed Faghihi Hospital
Full name of responsible person
Farzam Ahmadipoor
Street address
Shaheed Faghihi Hospital, Zand Blvd., Shiraz
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faghihi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sharareh Roshanzamir
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crc@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sharareh Roshanzamir
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Rehabilitation management
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Person responsible for scientific inquiries

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Shiraz University of Medical Sciences
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Position

Medical Student

Latest degree
A Level or less

Other areas of specialty/work
Medical Education

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Person responsible for updating data

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A Level or less

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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
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable