

# 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  $\geq 200$  mm Hg or diastolic blood pressure  $\geq 110$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1726 2850

##### Email address

nikaeinf@sums.ac.ir

##### 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  $\geq$  200 mm Hg. Diastolic blood pressure  $\geq$  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

**City**

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71348714737

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+98 71 3212 7001

**Email**

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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Shaheed Faghihi Hospital, Zand Avenue

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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

**Street address**

Shiraz-Zand St.-Shaheed Faghihi Hospital, Department of Rehabilitation

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nikaefinf@sums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzam Ahmadipoor

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Education

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Hospital, Zand St.

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Farzam Ahmadipoor

**Position**

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**Latest degree**

A Level or less

**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**

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