

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 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

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

Shiraz

Province

Fars

Postal code

71348714737

Phone

+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

Street address

Shaheed Faghihi Hospital, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3231 9040

Email

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

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3231 9040

Email

nikaeinf@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

Street address

Department of Rehabilitation, Shahid Faghihi
Hospital, Zand St.

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3231 9040

Email

nikaeinf@sums.ac.ir

Person responsible for updating data

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

Street address

Department of Rehabilitation, Shahid Faghihi
Hospital, Zand St.

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3231 9040

Email

nikaeinf@sums.ac.ir

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