

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

investigation of the effect of acupuncture on post-op chest pain after open heart surgery

Protocol summary

Study aim

Determination of the effect of acupuncture on chest pain in postoperative heart surgery

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

In this study, 30 patients who undergo open heart surgery referred to the Rehabilitation Center for Cardiac Rehabilitation in the Shahid Faghihi Hospital of Shiraz were enrolled in this study. For 15 randomly selected intervention groups, acupuncture performed at cardiac meridian for 30 minutes in 10 sessions, and for control group acupuncture was not performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients who undergo CABG

Exclusion criteria: 1-lack of patient collaboration for continuing acupuncture sessions 2-uncontrolled arrhythmia 3-decompensated heart failure 4-AV block 3rd degree 5-Acute systemic disease or fever 6--presence of any scar,inflammations or skin lesion on related acupuncture points

Intervention groups

The 15 patients undergoing acupuncture at the points of the heart meridian with Needle size of 0.3-1 CUN are given vertically for 30 minutes and 10 sessions, and this treatment was not performed for 15 subjects who form the control group. prescribing pain medications (acetaminophen) for both groups will be used to control pain according to need.

Main outcome variables

1-The comparison of mean pain before and after acupuncture in the study group 2-Comparison of the mean of pain in the study and control groups

General information

Reason for update

correction of the recruitment times (start and end dates)

Acronym

IRCT registration information

IRCT registration number: **IRCT20180530039913N1**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **prospective**

Last update: **2022-10-23, 1401/08/01**

Update count: **1**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Yas Haririan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3638 0391

Email address

haririany@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation of the effect of acupuncture on post-op chest pain after open heart surgery

Public title

Acupuncture for pain relief

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who undergo CABG

Exclusion criteria:

Lack of patient collaboration for continuing acupuncture sessions
Uncontrolled arrhythmia
Decompensated Heart failure
AV block 3rd degree
Acute systemic disease or fever
Presence of any scars , inflammation or skin tag on related acupuncture points

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

1)the study group doesnt know that acupuncture really was done on specific meiridan that related to cardiac pain or no? 2) the personnel doesn't have accurate informations about cardiac meridian that related to pain

Placebo

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

Shiraz, Zand Avenue - Central building of the University of Science Shiraz Medical Center - Seventh Floor - Vice-Chancellor for Research and Technology

City

shiraz

Province

Fars

Postal code

۷۴۳۳۶ - ۷۱۳۴۸

Approval date

2018-05-29, 1397/03/08

Ethics committee reference number

IR.SUMS.MED.REC.1397.108

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

investigation of the effect of acupuncture on post-op chest pain after open heart surgery

ICD-10 code

G89.12

ICD-10 code description

Acute post-thoracotomy pain

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

Chest pain after postoperative heart surgery based on VAS questionnaire

Timepoint

Determine the amount of pain after the end of each acupuncture session in the control group in the study group

Method of measurement

VAS score questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Intervention group: In the intervention group, for 15 patients, acupuncture was performed at the points of the cardiac Meridian with Needel size 0.3-1 CUN vertically for 30 minutes and 10 sessions Meridian related to cardiac pain : HT3 ,HT4,HT5,HT6,HT7, PC3,PC5,PC6,PC7

Category

Placebo

2**Description**

Control group: for control group also started treatment (acetaminophen 500 mg at pain every 6 hours) and finally, by completing the VAS score questionnaire, based on the statistical analysis, we compared the statistical data of the two groups

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac Rehabilitation Center of Shahid Faghihi Hospital of Shiraz

Full name of responsible person

Sharareh roshanzamir

Street address

Shiraz - Karim Khan Zand Boulevard - next to the Shiraz university of Medical sciences

City

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7134844119

Phone

+98 71 3235 1087

Email

faghihihsp@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

Shiraz, Zand Avenue, opposite Palestine Street, Central Building of Shiraz University of Medical Sciences

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info@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

Assistant Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Sharareh roshanzamir

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Person responsible for updating data

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Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Phone

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available