Clinical Trial Protocol
Iranian Registry of Clinical Trials
12 Aug 2019

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

Acronym
IRCT registration information
IRCT registration number: IRCT20180530039913N1
Registration date: 2018-09-04, 1397/06/13
Registration timing: registered_while_recruiting

Last update: 2018-09-04, 1397/06/13
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<td>Blinding (investigator’s opinion)</td>
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<td>1) the study group doesn’t know that acupuncture really was done on specific meridian that related to cardiac pain or not? 2) the personnel doesn’t have accurate informations about cardiac meridian that related to pain</td>
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### 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
- ۸۴۳۱۷ - ۶۳۳۴۱

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
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

City
shiraz

Province
Fars

Postal code
7134844119

Phone
+98 71 3235 1087

Email
sharareh.roshanzamir@gmail.com

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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Email
sharareh.roshanzamir@gmail.com

Person responsible for scientific 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

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Person responsible for updating data

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
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