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
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 doesn’t know that acupuncture really was done on specific meridian 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
84317 - 63341

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 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

Other areas of specialty/work
Physical Medicine

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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
Physical Medicine

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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