

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Investigating the effect of acupressure on pain Severity in patients undergoing coronary artery graft surgery hospitalized in cardiac intensive care unit

#### Protocol summary

##### Study aim

Determining the effect of acupressure on the severity of pain in patients undergoing coronary artery bypass graft, hospitalized in Shahid Chamran cardiac intensive care unit in Isfahan, 2017

##### Design

This study is a randomized clinical trial. The sampling will be done by stratified randomization method, so that the two studied groups are matched in terms of gender and pain severity.

##### Settings and conduct

This study will be performed on patients undergoing coronary artery bypass graft surgery in the Cardiology Department of Shahid Chamran Hospital affiliated to Isfahan University of Medical Sciences, Iran. Patients who have the inclusion criteria will be randomly assigned into two intervention (by acupressure) and control (touch) groups. The severity of pain in two groups will be compared before and after the intervention. The person who will assess the severity of pain will be blind in identifying the type of sample group.

##### Participants/Inclusion and exclusion criteria

The participants included all patients undergoing coronary artery bypass grafting that hospitalized in Shahid Chamran cardiac intensive care unit in Isfahan, who have the cognitive, psychological and physical ability to answer research questions and collaborate with the researcher and also informed consent to participate in the study. Patients with deformity at the LI4 acupressure point or with advanced neuropathy, as well as a history of open heart surgery or the history of using acupressure will not be included in the study.

##### Intervention groups

In the intervention group, after complete consciousness, extubation and the stability of the vital signs, the bilateral pressure at the LI4 point, will be applied for 20 seconds. In the control group, at the same points and

within the same time, the touch without the pressure will be carried out.

##### Main outcome variables

pain severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170826035913N2**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **retrospective**

Last update: **2018-04-24, 1397/02/04**

Update count: **0**

##### Registration date

2018-04-24, 1397/02/04

##### Registrant information

##### Name

Tayebe Negahban Bonabi

##### Name of organization / entity

Rafsanjan University of Medical Sciences, School of Nursing and Midwifery

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

negahbant@rums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

The financial source of the Rafsanjan University of Medical Sciences project.

##### Expected recruitment start date

2017-09-23, 1396/07/01  
**Expected recruitment end date**  
2017-11-22, 1396/09/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Investigating the effect of acupressure on pain Severity in patients undergoing coronary artery graft surgery hospitalized in cardiac intensive care unit

**Public title**  
The effect of acupressure on postoperative pain in coronary artery bypass graft surgery

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

In this study, patients will be enrolled in the study with the following conditions : Stability of vital signs, no history of using acupressure for any purpose ,no scars, scratches and deformities at the point LI4 , ability to speak and understand Persian language, absence of hearing impairment, no connection to the ventilator , complete consciousness ,no tracheal tube , no history of open heart surgery ,no history of mental illness ,having informed consent to participate in the study absence of advanced neuropathy, no addicted

**Exclusion criteria:**

Hearing Impairment Connecting to the Ventilator Having tracheal Intubation History of Open Heart Surgery History of Mental Illness Advanced Nephropathy Addiction Scars, scratches and deformities at the point LI4 history of using acupressure for any purpose

**Age**  
From **30 years** old to **80 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, sampling will be carried out by the stratified random sampling. The strata will be formed based on the severity of pain (in three mild, moderate and severe classes) and sex (in two male and female classes) for both groups(intervention and control). Entering the first sample in each of the classes will be by the simple randomization. For subsequent samples, the sum of the samples in the groups will be considered, so that the sample is assigned to a group that that has less sample size. Sampling will continue until the sample size

reaches the target.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
A person who assesses the severity of pain does not know about belonging to the groups

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical Sciences

**Street address**

Central Office of Rafsanjan University of Medical Sciences, Imam Ali Blvd, Rafsanjan, Kerman Province, Iran

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2017-08-06, 1396/05/15

**Ethics committee reference number**

IR.RUMS.REC.1396.73

**Health conditions studied**

1

**Description of health condition studied**

Coronary Artery Bypass

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

the pain

**Timepoint**

Before the intervention - immediately after the intervention -30 minutes after the intervention

**Method of measurement**

Using the VAS scale

## Secondary outcomes

### 1

#### Description

The frequency of patient's need for pain relief

#### Timepoint

The first 24 hours after the intervention

#### Method of measurement

Record the frequency of analgesic use for the patient

## Intervention groups

### 1

#### Description

In the intervention group: after the patient's complete consciousness and extubation of the trachea, which is routinely 6 to 7 hours after the surgery. The severity of the pain will be measured by the researcher's colleague before the intervention. Then one of the researchers who have enough training in acupuncture will face the patient and in the LI4 point will be applied acupuncture bilaterally for 20 minute period, so that in each minute, 5 pressure periods will be applied at the LI4 point. Each cycle will consist of 10 seconds of pressure and 2 seconds of rest. The applied pressure will be about 3-5 kg, so that the patient feel warmth, pressure and have numbness at that pressure point.

#### Category

Other

### 2

#### Description

Control group: In the control group, after complete consciousness and ex-tubation of the patient, the severity of pain before the intervention will be measured by the researcher's colleague. Then the researcher will face the patient. At the same pressure point, same as the intervention group, by the same time, the touch without pressure will be applied.

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Chamran Hospital

##### Full name of responsible person

Maryam Narimani

##### Street address

Salman Farsi Street after the City Bridge-Shahid Chamran Hospital. Isfahan, Iran

##### City

Esfahan

##### Province

Isfahan

##### Postal code

7718796755

##### Phone

+98 34 3425 5900

##### Email

narimani4@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Ali Shamsizadeh

##### Street address

Central office of Rafsanjan University of Medical Sciences, Imam Ali Blvd, Rafsanjan, Kerman Province, Iran

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

##### Phone

+98 34 3428 0040

##### Fax

+98 34 3428 0097

##### Email

vcrt@rums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

##### Full name of responsible person

Tayebeh Negahban Bonabi

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursing

**Street address**

Nursing & Midwifery Faculty, Parastar Street,  
Rafsanjan, Kerman Province, Iran

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

+98 34 3425 8497

**Email**

negahbant@rums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Tayebeh Negahban Bonabi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursing

**Street address**

Department of Community Health Nursing, Faculty of  
Nursing and Midwifery, Parastar ST, Rafsanjan,  
Kerman Province, Iran

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718766755

**Phone**

+98 34 3425 5900

**Fax**

**Email**

Negahbant@rums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Maryam Narimani Zaman Abadi

**Position**

MS.C. student in nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursing

**Street address**

Post Graduate Office, Faculty of Nursing and  
Midwifery, Parastar ST , Rafsanjan, Kerman Province,  
Iran

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Fax**

**Email**

maryam.narimani4@gmail.com

**Web page address**

**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