

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparing the effects of therapeutic massage by nurses and patients' companion on pain severity and sleep quality in post CABG patients

#### Protocol summary

##### Summary

Objectives: The aim of this study is comparing the effects of massage therapy done by the nurse and by the patient's companion, on the pain intensity and sleep quality in post CABG patients. Design: Randomized controlled clinical trial study Setting and conduct: By convenience sampling, 105 patients the patients who will be randomly allocated in 3 groups. Eligibility criteria: Underwent CABG surgery; age between 18 and 70; hospitalization at least 3 days in cardiac surgery ward. exclusion criteria: Decrease level of consciousness; hemodynamic instability; unwillingness to continuing participation. Intervention: Before the intervention, pain intensity in incision site and sleep quality will be assessed. Massage will be done by the nurse in the first group and by patient's companion in the second group. Third group won't receive any intervention except routing care. Main outcome: Pain intensity will be assessed immediately, 30, 60, and 120 minutes after intervention. One day after second intervention, sleep quality will be assessed. Data analysis will be done by SPSS software by ANOVA and Scheffe assumptions test (LSD).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201208218505N3**

Registration date: **2013-12-24, 1392/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-12-24, 1392/10/03

##### Registrant information

##### Name

Seyed Saeed Najafi

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1727 7445

##### Email address

najafisa@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2012-10-22, 1391/08/01

##### Expected recruitment end date

2013-01-20, 1391/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effects of therapeutic massage by nurses and patients' companion on pain severity and sleep quality in post CABG patients

##### Public title

Comparing the effects of therapeutic massage by nurses and patients' companion on pain severity and sleep quality in post CABG patients

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

A) Inclusion criteria: 1- Orientation to time, place & person; 2 - Minimum age 18 and maximum 70; 3- Post CABG patients; 4- Patients hospitalized in post heart

surgery ICU and stay at least 3 days; 5- Willing to participate. B) Exclusion criteria:1- Unwillingness to continuing participation; 2- Decrease level of consciousness; 3- Unstable hemodynamic status; 4- Patients who have coagulation problems; 5- Pump time more than four hours; 6- Patients who have chronic and malignant pain; 7- prescription of sedative drugs (over 0.5 mg Alprazolam per day); 8- History of drug and alcohol abuse over the last two months; 9- History of diabetes over the last fifteen years; 10- History of neurological, cerebrovascular, cardiovascular, psychiatric and respiratory disorders.

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences Ethics Committee

**Street address**

7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Fars Province,

**City**

Shiraz

**Postal code**

1978-71345

**Approval date**

2012-10-03, 1391/07/12

**Ethics committee reference number**

ct-91-6260

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

coronary artery disease

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease

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

pain

**Timepoint**

before and immediately,30,60 minutes and 2 hours after the massage therapy

**Method of measurement**

visual analog scale

**2****Description**

sleep quality

**Timepoint**

before and one day after the last intervention

**Method of measurement**

SMHSQ

**Secondary outcomes**

empty

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

The first group (massage by the nurse): massage therapy will be done for 30 minutes by a nurse in the third and fourth post-op days. Pain severity will be assessed before, immediately, 30, 60, and 120 minutes after first massage therapy session. Sleep quality will be assessed before and one day after the last intervention.

**Category**

Behavior

**2****Description**

Group II (massage by the patient's companion): massage therapy will be done for 30 minutes by a patient's companion in the third and fourth post-op days. Pain severity will be assessed before, immediately,30, 60, and 120 minutes after first massage therapy session. Sleep quality will be assessed before and one day after the last intervention.

**Category**

Behavior

### 3

#### Description

Group III (control group): This group does not receive massage therapy, but in the third and fourth post-op days a nurse and a patient's companion remain with patient for 30 minutes. Pain severity will be assessed before, immediately, 30, 60, and 120 minutes after first session. Sleep quality will be assessed before and one day after last session.

#### Category

Behavior

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Namazi Hospital

###### Full name of responsible person

Sayed Saeed Najafi

###### Street address

Fateme (P.B.U.H.) school of nursing & midwifery,  
Namazi square, Shiraz

###### City

Shiraz

#### 2

##### Recruitment center

###### Name of recruitment center

Shahid Faghihi Hospital

###### Full name of responsible person

Sayed Saeed Najafi

###### Street address

Karim- Khan Zand Blvd.

###### City

Shiraz

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice chancellor for research, Shiraz University of  
Medical Sciences

###### Full name of responsible person

Gholamreza Hatam

###### Street address

7th floor, Central Building of Shiraz University of  
Medical Sciences, Zand Street, Shiraz. Shiraz Fars  
Iran, Islamic Republic Of

###### City

Shiraz

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Vice chancellor for research, Shiraz University of Medical  
Sciences

###### Proportion provided by this source

100

###### Public or private sector

empty

###### Domestic or foreign origin

empty

###### Category of foreign source of funding

empty

###### Country of origin

###### Type of organization providing the funding

empty

### Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical sciences

##### Full name of responsible person

Rast Fazlollah

##### Position

Master of critical care nursing

##### Other areas of specialty/work

##### Street address

Fateme (P.B.U.H.) school of nursing & midwifery,  
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### Person responsible for scientific inquiries

#### Contact

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##### Position

MS in nursing - Faculty member

##### Other areas of specialty/work

##### Street address

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Fateme (P.B.U.H.) school of Nursing & Midwifery

**Full name of responsible person**

Rast Fazlollah

**Position**

Master of science on critical care nursing

**Other areas of specialty/work**

**Street address**

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**Web page address**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*