

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,
Namazi square, Shiraz

City

Shiraz

Postal code

71936-13119

Phone

+98 71164742546

Fax

+98 71 1647 4252

Email

fazlrast@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sayed Saeed Najafi

Position

MS in nursing - Faculty member

Other areas of specialty/work

Street address

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

City

Shiraz

Postal code

71936-13119

Phone

+98 71164742546

Fax

+98 71 1647 4252

Email

s_najafi44@yahoo.com

Web page address

<http://nurs-midwif.sums.ac.ir>

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

Fateme (P.B.U.H.) school of Nursing & Midwifery,
Namazi square, Shiraz

City

Shiraz

Postal code

71936-13119

Phone

0711 -10987116474254-6

Fax

+98 71 1647 4252

Email

Fazlrast@yahoo.com

Web page address

<http://nurs-midwif.sums.ac.ir>

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