Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of foot reflexology massage on pain, fatigue and physiological parameters in patients on pump and off pump coronary artery bypass graft in medical centers in Shiraz in 2015

Protocol summary

Summary

The aim of this study was to determine the effect of foot reflexology massage on pain, fatigue and physiological parameters in patients with coronary artery bypass surgery medical centers in Shiraz as effective if the massage effect on pain, fatigue and physiological indicators have as a complementary method to be used alongside drug therapy. Study design: inclusion criteria included; the aged 18 years and older; full consciousness after the operation, lack of suffering from sensorimotor and lack hearing and eyesight disorders. Exclusion criteria included; the patient's consent to continue participating in the study, having a pacemaker and a balloon pump, having an arterial line in the leg, blood disorders and thrombocytopenia. The study is a randomized controlled clinical trial with 100 patients that they were allocated based on the stratified block randomization into 2 equal groups: experimental group and control group (n=50) that both groups included patients on pump and off pump coronary artey bypass graft (n=25). The experimental group consisted of 30 minutes massage for the patient, preferably in the left foot on the second day after the operation at the end of the evening shift will be made by the researcher female and male research assistant. Pain and fatigue level will be measured by McGill pain questionnaire and Numerical Rating Scale (NRS) and also physiological parameters in two group at 10 minutes before and at 10 minutes, 30 minutes and 24 hours after the intervention. In the control group, the patient's foot will be touched only 30 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112122466N7**

Registration date: **2015-12-26, 1394/10/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Shahnaz Pouladi

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 917 374 0061

Email address

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences Bushehr, Vice chancellor for research

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of foot reflexology massage on pain, fatigue

and physiological parameters in patients on pump and off pump coronary artery bypass graft in medical centers in Shiraz in 2015

Public title
The effect of foot reflexology massage on pain, fatigue and physiological parameters in patients CABG
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria included; Patient willingness to participate in the study, being first heart surgery, elective open heart surgery, age 18 and older, The absence of deformity and structural deformity in the legs, full consciousness after surgery, not addicted to drugs or alcohol and etc, lack of suffering from sensorimotor disorders, lack of hearing and vision disorders, no history of foot reflexology. Exclusion criteria included; having arterial line in foot, blood disorders and thrombocytopenia, need to intra-aortic balloon pump, intubated for more than 24 hours, bleeding more than 200 ml per hour of chest tubes, perform repair or replace the valve with CABG, wound infection and skin disease in the legs, having cardiac pacemaker, remobilization to the intensive care unit for further treatment, lack of consent to continue participating in the study, lack of access to suitable environmental conditions for intervention during the investigation.
Age
From **18 years** old to **100 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bushehr University of Medical Sciences
Street address
Bushehr University of Medical Sciences , Sabzabad, Bushehr
City
Bushehr
Postal code
Approval date
2015-11-16, 1394/08/25
Ethics committee reference number
IR.bpums.rec.1394.25

Health conditions studied

1

Description of health condition studied
CABG
ICD-10 code
T82.9
ICD-10 code description
T82.9 Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
pain
Timepoint
Ten minutes before and at 10 minutes, 30 minutes and 24 hours after the intervention
Method of measurement
McGill pain questionnaire and Numerical Rating Scale (NRS)

2

Description
Fatigue
Timepoint
Ten minutes before and at 10 minutes, 30 minutes and 24 hours after the intervention
Method of measurement
Numerical Rating Scale (NRS)

3

Description
Physiological parameters
Timepoint
Ten minutes before and at 10 minutes, 30 minutes and 24 hours after the intervention
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The experimental group consisted of 30 minutes massage for the patient, preferably in the left foot on the second day after the operation at the end of the evening shift will be made by the researcher female and male researcher assistant. Pain and fatigue levels will be measured by McGill pain questionnaire and Numerical Rating Scale (NRS) and also physiological parameters in two groups at 10 minutes before and at 10 minutes, 30 minutes and 24 hours after the intervention.
Category
Treatment - Other

2

Description
In the control group, the patient's foot will be touched only 30 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Martyr Beheshti Hospital
Full name of responsible person
Somayeh Mohammadi, Nursing Graduate Student
Street address
Vali Asr Square, Shiraz
City
shiraz

2

Recruitment center
Name of recruitment center
Shiraz Nemazee Hospital
Full name of responsible person
Somayeh Mohammadi, Nursing Graduate Student
Street address
Nemazee Square, Shiraz
City
shiraz

3

Recruitment center
Name of recruitment center
Shiraz Martyr Faghihi Hospital
Full name of responsible person
Somayeh Mohammadi, Nursing Graduate Student
Street address
Zand Blvd, Shiraz
City
Ṣhiraz

4

Recruitment center
Name of recruitment center
Shiraz Alzahra Heart Charity Hospital
Full name of responsible person
Somayeh Mohammadi, Nursing Graduate Student
Street address
Sibawayh Blvd, Shiraz
City
Shiraz

5

Recruitment center
Name of recruitment center
Shiraz Kosar Hospital
Full name of responsible person
Somayeh Mohammadi, Nursing Graduate Student
Street address
Ghasroddasht Blvd, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Medical Sciences Bushehr, Vice chancellor for research
Full name of responsible person
Dr.Afshin Ostovar
Street address
Vice chancellor for research, Bushehr University of Medical Sciences , Sabzabad, Bushehr
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Medical Sciences Bushehr, Vice chancellor for research
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

Bushehr University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Pouladi

Position

Nursing Ph.D.

Other areas of specialty/work

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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