

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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 artery 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)

Phone

+98 917 374 0061

Email address

sh.pooladi@bpums.ac.ir

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	
<u>1</u>	
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	
<u>1</u>	
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	
<u>1</u>	
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)
<u>2</u>	
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)
<u>3</u>	
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

Shiraz

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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Web page address

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