

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Protocol summary

Summary

Background: Pain and fatigue are complications after coronary artery bypass graft surgery. Because of non-pharmacological methods are the preferred pharmacological agent therefore; the purpose of this study was assessment of effect of foot reflexology on pain and fatigue in patients undergoing CABG. Methods: This study was a randomized controlled clinical trial, conducted on 80 patients hospitalized in the Heart Center of Mazandaran in 2011. Sampling was in manner of Non-random and accessible. Patients were age and sex matched and divided randomly in two equal groups of case and control. The reflexology group received 20-minutes left foot massage, from the second day after surgery for 4 consecutive days. In the control group, patient's left foot without applying any pressure and only for 1 minute was fat. Variables pain and fatigue before and after the intervention was recorded by the use of visual analogue scale at the time mentioned. The findings were analyzed by using the software SPSS version 17, descriptive and inferential statistics and tests of χ^2 and Repeated measurements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109067494N1**

Registration date: **2012-05-30, 1391/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2011-09-08, 1390/06/17

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Public title

The effect of foot reflexology massage on pain, anxiety and fatigue in patients undergoing coronary artery bypass surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: first candidate for open heart surgery (CABG); under non-emergency heart-lung pump.

Exclusion criteria: lack of patient satisfaction on the

ongoing research; lack of consciousness; the need to intra aorta pump; intubation of more than 24 hours; bleeding more than 200 cc per hour of chest tube; Performed surgery to repair or replace the valve with CABG; severe visual impairment; history of chronic pain; alcohol and drug addiction; drug addiction 4 hours before; having fractures; infected wounds and skin diseases in the left leg; severe disorders of hearing and visual; covered the sole of the left foot with dressing; remove the graft from the left foot and left sole are in the presence of any sensory impairment.

Age

From **40 years** old to **78 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.

City

sari

Postal code

4816715793

Approval date

2011-09-07, 1390/06/16

Ethics committee reference number

90-88

Health conditions studied

1

Description of health condition studied

coronary artery by pass graft

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Pain after coronary artery bypass graft surgery

Timepoint

The second day, third, fourth and fifth after the surgery and immediately after each intervention.

Method of measurement

Visual Analog Scale

2

Description

Anxiety after coronary artery bypass graft surgery

Timepoint

The second day, third, fourth and fifth after the surgery and immediately after intervention

Method of measurement

Visual Analog scale

3

Description

Fatigue after coronary artery bypass graft surgery

Timepoint

The second day, third, fourth and fifth after the surgery and immediately after each intervention.

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description

Foot reflexology massage in the case group 20 minutes on the second, third, fourth and fifth after coronary artery bypass graft surgery

Category

Treatment - Other

2

Description

In the control group, only the left foot with fatty cream and researcher was present for 20 minutes on the second day, third, fourth and fifth postoperative coronary artery graft surgery on the patient's bedside

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemeh zahra hospital

Full name of responsible person

Masoumeh Bagheri Nesami

Street address

Mazandaran University of Medical Sciences, three-way Joibar, highway Basij, Imam square, Sari, mazandaran, Iran.

City

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Dr. Ahmahali Enayati

Street address

Mazandaran University of Medical Sciences, Vice chancellor for research, Moalem street, Moalem square. , Sari, mazandaran, Iran.

City

Sari

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 of Mazandaran University of Medical Science

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****Person responsible for scientific inquiries****Contact****Name of organization / entity****Full name of responsible person****Position****Other areas of specialty/work****Street address****City****Postal code**

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Web page address**Person responsible for updating data****Contact****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