

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effects of Foot Reflexology on Post-Sternotomy Hemodynamic Status and Pain in Patients Undergoing Coronary Artery Bypass Graft

Protocol summary

Study aim

Effects of Foot Reflexology on Post-Sternotomy Hemodynamic Status and Pain in Patients Undergoing Coronary Artery Bypass Graft

Design

This study is a randomized clinical trial, single blinded with parallel groups and control group.

Settings and conduct

The left foot sole was massaged for 15 minutes. It began with massaging the place where the toes are connected to the rest of the foot below the third toe line by the heel of the hand from the center of the foot outwards. The solar plexus reflex point, where the foot meets the foot arch, was then pressed and massaged using both tips of the thumbs by rotational motions from the center of the foot outwards for 30 seconds. Finally, the center of foot sole was massaged by the thumb using rotational motions with tolerable pressure so that it would not annoy the patient. The massage was performed in 20 minutes

Participants/Inclusion and exclusion criteria

Inclusion criteria: being candidate for coronary artery bypass graft; full foot health Exclusion criteria: blood disorders and thrombocytopenia

Intervention groups

The patient in the test group received 20 minutes of left foot reflexology based on the existing method and those in the control group received no intervention

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N9**

Registration date: **2019-09-04, 1398/06/13**

Registration timing: **prospective**

Last update: **2019-09-04, 1398/06/13**

Update count: **0**

Registration date

2019-09-04, 1398/06/13

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-11, 1398/06/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Foot Reflexology on Post-Sternotomy Hemodynamic Status and Pain in Patients Undergoing Coronary Artery Bypass Graft

Public title

Reflexology Effects on Post-Sternotomy Pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Coronary artery graft candida Full foot health

Exclusion criteria:

Blood disorders and thrombocytopenia

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were selected using purposive sampling and were then randomly assigned to the two groups using a random number table

Blinding (investigator's opinion)

Single blinded

Blinding description

The data analyzer does not know the type of grouping of people and is blind to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TBZMED.REC.1397.1059

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description

Pain

Timepoint

Daily

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: the left foot sole was massaged for 15 minutes. It began with massaging the place where the toes are connected to the rest of the foot below the third toe line by the heel of the hand from the center of the foot outwards. The solar plexus reflex point, where the foot meets the foot arch, was then pressed and massaged using both tips of the thumbs by rotational motions from the center of the foot outwards for 30 seconds. Finally, the center of foot sole was massaged by the thumb using rotational motions with tolerable pressure so that it would not annoy the patient. The massage was performed in 20 minutes

Category

Prevention

2

Description

Control group: those in the control group received no massage

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital

Full name of responsible person

Mehdi Khanbabayi Gol

Street address

Azadi Ave, Shahid Madani Hospital

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

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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Childrens Hospital, Sheshgelan Ave

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available