

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the Effectiveness of transcutaneous electrical nerve stimulation and foot reflexology on pain and fatigue in patients after Coronary artery bypass graft surgery

Protocol summary

Study aim

Comparison effectiveness of tens and foot reflexology on pain and fatigue in patients after coronary artery bypass graft surgery

Design

A clinical trial with community-based and pragmatic control group was randomized with two blind non-blind random groups with a total volume of 75 patients with coronary artery bypass graft surgery

Settings and conduct

This study was performed on patients undergoing coronary artery bypass graft surgery in Imam Reza Hospital in Mashhad, 1397-1396 will be done. Each group will consist of men and women equally from the age of 80 to 30 years. first group, after 4 hours of receiving the most common reflexology foot massage, the second group received 4 hours after receiving the usual dentistry, electrical stimulation of the skin, and in the third group, no intervention was performed and according to the common routine in the section Will receive. After the interventions, the patient's pain and fatigue are measured using the VAS scale. Correcting is not done.

Participants/Inclusion and exclusion criteria

Entry conditions study having satisfaction for the study, Age between 30 and 80, Patients who are fully conscious and full health of the foot. Patients have the ability to read and write. Patients with on allergy to gel electrode. no entry conditions study sensitivity to touch and massage. Sensory disturbances on the foot of the leg, History of using palpable reflexes or skin electrical stimulation, Psychological and cognitive disorders. Having a pacemaker heart. Drug addiction, alcoholism, diabetes over 4 years, Having blood disorders

Intervention groups

In this study there were three groups: in the first group reflexology, in the second group skin electrical

stimulation and control group It does not take place.

Main outcome variables

, the pain , fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180220038805N1**

Registration date: **2018-05-01, 1397/02/11**

Registration timing: **prospective**

Last update: **2018-05-01, 1397/02/11**

Update count: **0**

Registration date

2018-05-01, 1397/02/11

Registrant information

Name

Soghra Taghizadehmehneh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4722 2411

Email address

taghizades95@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of transcutaneous electrical nerve stimulation and foot reflexology on pain and fatigue in patients after Coronary artery bypass graft surgery

Public title

Comparison of the Effectiveness of transcutaneous electrical nerve stimulation and foot reflexology on pain and fatigue in patients after Coronary artery bypass graft surgery"

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having satisfaction for the study Patients who are fully conscious of the full leg of their legs Patients have the ability to read and write Ability to understand and speak Persian Patients with an allergy to gel electrode Having age between 30 and 80

Exclusion criteria:

Sensitivity to touch and massage Sensory disturbances on the foot of the leg History of using palpable reflexes or skin electrical stimulation Psychological and cognitive disorders Having a pacemaker heart Bradycardia (less than 60 beats per minute) and hypotension (blood pressure less than 90 mm Hg) Drug addiction, alcoholism and alcoholism The history of diabetes over 4 years Having blood disorders

AgeFrom **30 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

Assignment of samples will be done by the method of permutation blocks. In this method, the number one to the Massage intervention group. The number two will be allocated to the Tens group and the three to the control group. In this way, the blocks of six are formed and all the necessary permutations are listed Then one will be chosen from among them.

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 Sabzevar University of Medical Sciences

Street address

University of Medical Sciences, Tohid Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9523459876

Approval date

2018-02-18, 1396/11/29

Ethics committee reference number

IR.MEDSAB.REC.1396.144

Health conditions studied**1****Description of health condition studied**

Patients with coronary artery bypass surgery

ICD-10 code

I79*

ICD-10 code description

Disorders of arteries, arterioles and capillaries in diseases classified elsewhere

Primary outcomes**1****Description**

Fatigue is an unpleasant sensation experienced by patients after coronary artery bypass graft surgery and measured by Visual Analogue scale.

Timepoint

Before the intervention, immediately after intervention and half an hour later intervention

Method of measurement

Using Visual Analogue Scale

Secondary outcomes**1****Description**

The pain is experienced by patients after coronary artery bypass surgery and measured by Visual Analogue Scale scale.

Timepoint

Before the intervention, immediately after intervention and half an hour later intervention

Method of measurement
Using Visual Analogue Scale

Intervention groups

1

Description

Intervention group: First: In this group, the foot massage will be performed, this intervention will be performed once for 20 minutes per foot for 10 minutes. Intervention by the researcher and for the men by the partner's colleague, both of whom have already been fully trained by the relevant specialist. Performing massage with a reflexology stick, called a stick, will be done. The styx, a standard device with soft, trendy feet used to massage the soles of the foot, is a tool made in China and has been used to do it since ancient times. Reflexology has been used. Before the start and during the work, the conditions of the room, the conditions of the research unit and the conditions of the researcher will be taken into account: the room temperature will be kept to a balanced level.

Category

Rehabilitation

2

Description

Intervention group: Second: In the second group, the Tens model med450, which is made by Iran, will be used. Due to the presence of electrodes and the possibility of patient's fear, it will be fully explained to the patient, which will have no complications. The electrodes are connected around the wound area and run at equal frequencies for all patients and equal flow intensity during 15 minutes of intervention. This will be done by the researcher himself and for everyone with a device.

Category

Rehabilitation

3

Description

Control group: Third: No intervention is possible

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mojtaba Rad

Street address

Ibn Sina street, the edge of Imam Reza Square

City

Mashad

Province

Razavi Khorasan

Postal code

9562348993

Phone

+98 51 3854 3031

Email

Taghizades95@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Abdolghader Assarrudi

Street address

University of Medical Sciences, Tohid Town

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Phone

+98 51 4401 3001

Email

Gaderassar@yahoo.com

Web page address

<http://www.medsab.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mojtaba Rad

Position

science Committee

Latest degree

Master

Other areas of specialty/work

Nursery
Street address
University of Medical Sciences, Tohid Township
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 3001
Email
rad.mojtaba89@yahoo.com
Web page address
<http://www.medsab.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Soghra Taghizadeh Mehneh
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
University of Medical Sciences, Tohid Township
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 44013001
Email
Taghizades95@medsab.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Soghra Taghizadeh Mehneh

Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
University of Medical Sciences, Tohid Township
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613873136
Phone
+98 51 4401 3001
Email
Taghizades95@medsab.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data after unidentifiable individuals can be shared.

When the data will become available and for how long

Since 1397

To whom data/document is available

All people

Under which criteria data/document could be used

To read and mention the source

From where data/document is obtainable

Taghizades95@medsab.ac.ir

What processes are involved for a request to access data/document

Apply to an email to be answered within 3 days.

Comments