Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
Age
From **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
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9562348993
Phone
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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
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University of Medical Sciences، Tohid Town
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Phone
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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
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University of Medical Sciences، Tohid Township
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Person responsible for scientific inquiries

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Soghra Taghizadeh Mehneh
Position
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Person responsible for updating data

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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