Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of foot reflexology on anxiety and physiological parameters of patients undergoing coronary artery bypass heart surgery in intensive care unit

Protocol summary

Summary

The aim of this study is to evaluate the effect of foot reflexology on anxiety and physiological parameters in patients undergoing coronary artery bypass heart surgery in intensive care unit. This study is a single blind randomized clinical trial. patients between 18 to 65 years of age who were admitted to shahid madani hospital and are on the list to perform non-emergency coronary artery bypass graft surgery and meeting the inclusion criteria such as no history of coronary artery bypass graft surgery,no psychologic problems and having healthy feet, after obtaining inform consent, will be enrolled in the study and placed in three groups of control, intervention (reflexology) and placebo (general massage) with a ratio of 1:1:1 using RandList software application. The sample size was calculated as 44 people for each group. During this study no patient will come to understand in which group he/she is. at first the anxiety and physiological parameters will be assessed using the related tools and intervention will be fulfilled, and Immediately and just 10 minutes after the intervention, the parameters will be measured. For the second and third days of hospitalization of patients in the intensive care unit, variables will be measured before ,immediately and 10 minutes after the intervention. Interventions include reflexology massage for intervention group and general massage for placebo group which will be done after lubricating hands with olive oil. The control group will receive a routine care.The main outcome variables in this study will be anxiety and physiological parameters which will be measured by their related tools.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110125937N3**

Registration date: **2017-01-30, 1395/11/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-30, 1395/11/11

Registrant information

Name

Aefeh Allahbakhshian

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Tabriz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on anxiety and

physiological parameters of patients undergoing coronary artery bypass heart surgery in intensive care unit

Public title
The effect of reflexology on anxiety and physiological parameters of coronary artery bypass surgery patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: 1) Having age between 18 to 65 and women after menopause to prevent the effects of hormones on blood vessel walls due to the effects on hemodynamic parameters such as heart rate and blood pressure. 2) No previous history of coronary artery bypass surgery. 3) No emergency bypass surgery. 4) Identical conditions of anesthesiologists and anesthesia for all patients. 5) Surgery with the heart and lungs device. 6) No psychological problems (such as depression or anxiety disorders), and history of psychiatric drugs according to the patient's previous history and the patient's clinical records. 7) No reflexology for at least the last 3 months. 8) Having healthy feet and no foot deformities (such as corns, callus, previous scar, neuropathy). 9) Having neither an intra-aortic balloon pump nor a pacemaker. 10) No addiction to alcohol and drugs. 11) No history of chronic pain such as arthritis. 12) Not participated in a similar study. 13) No facial scar. Exclusion criteria: 1) Lack of consciousness 2) Heart valve repair or replacement during CABG surgery. 3) Severe visual impairments after surgery. 4) Hemodynamic instability. 5) Dissatisfaction to continue to participate in the study
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Random allocation is done using computer random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Golgasht ave., Tabriz, Iran.
City
Tabriz
Postal code
5165665931
Approval date
2016-12-12, 1395/09/22
Ethics committee reference number
1395.931.IR.TBZMED.REC

Health conditions studied

1

Description of health condition studied
Ischemic Heart Disease
ICD-10 code
125.8
ICD-10 code description
Other forms of chronic ischaemic heart disease

Primary outcomes

1

Description
Anxiety
Timepoint
Before the intervention, immediately after intervention, and ten minutes after intervention
Method of measurement
Anxiety Visual Scale

Secondary outcomes

1

Description
Physiological parameters
Timepoint
Before the beginning of intervention then immediately and 10 minutes after intervention
Method of measurement
Physiological Index Documentation Form

Intervention groups

1

Description
Foot reflexology for intervention group.

Category
Treatment - Other

2

Description
Foot general massage for placebo group
Category
Treatment - Drugs

3

Description
Routine care for control group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences
Full name of responsible person
Dr Atefeh Allahbakhshian
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Sponsors / Funding sources

1

Sponsor
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Dr Mohammadreza Rashidi
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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
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
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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