

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of foot reflexology on fatigue, pain and physiological parameters in patients after coronary angiography

Protocol summary

Summary

This study is a clinical trial to determine The Effect of foot reflexology on Fatigue and pain and physiological parameters of Hospitalized patients after coronary angiography in Baqiyatallah educational-therapeutic and research center ., Inclusion criteria included: Age of 75 -18 years, Heart rate above the 60 beats per minute and systolic blood pressure above the 90 mm Hg, Not arrhythmia, , Absence of history of coronary angiography and Using reflexology. Study exclusion criteria included:lack of patient consent to continue participating in the study, and CPR for patient bleeding. The sample of study included 70 patients and satisfied to participate in the study. The sample are selected with random sampling and using the method of putting the Random blocks in two groups (35 people), reflexology and a control group (usual care) . Fatigue, Pain and physiologic parameters(systolic and diastolic blood pressure , pulse rate, respiratory rate) Questionnaire is measured by collaborator 2 hours after angiography. In reflexology group, massage is done by researcher (and man collaborator for male patients) for 10 minutes. The sequence are used of relaxation and specific areas of the heart. Stages of massage include: - Rhythmic ankle rotation, Wringing the foot, massage of solar plexus, pituitary, and heart. Fatigue and pain and physiologic parameters Questionnaire is recorded and assessed by collaborator ,2 hours after angiography and 2 and 4 hours after the procedure again. In the control group intervention will not occur, except routine care and vital signs measurement . Fatigue and pain and physiologic parameters Questionnaire recorded by collaborator and with presence of researcher at intervals corresponding test groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015072223286N1**

Registration date: **2016-04-08, 1395/01/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-08, 1395/01/20

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Department of Science and Technology of Tehran University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on fatigue, pain and

physiological parameters in patients after coronary angiography		Postal code 1419733171
Public title The effect of foot reflexology on fatigue, pain and physiological parameters in patients after coronary angiography		Approval date 2015-12-15, 1394/09/24
Purpose Supportive		Ethics committee reference number IR.TUMS.REC.1394.1407
Inclusion/Exclusion criteria Inclusion criteria: willingness to participate in research ; non-emergency angiography ; The age range of eighteen to seventy-five years ; No disturbance of consciousness ; Lack of vascular injuries of the lower limbs and sensory-motor disorders of the feet (especially Diabetic Foot) ; The absence of abnormalities such as corns, burns, amputations and skin disorders in the legs ; lack of inter-vertebral disc herniation, low back pain and back pain Exclusion criteria: Failure to consent to continued participation ; Death participants ; hemodynamic instability (dysrhythmia, respiratory disorders, and severe changes in blood pressure requiring emergency interventions ; bleeding after angiography		Health conditions studied
Age From 18 years old to 75 years old		1 Description of health condition studied Fatigue ICD-10 code F48.8 ICD-10 code description Other specified neurotic disorders
Gender Both		2 Description of health condition studied Pain ICD-10 code R52.0 ICD-10 code description Acute pain
Phase N/A		3 Description of health condition studied Angiography ICD-10 code R93.1 ICD-10 code description Abnormal findings on diagnostic imaging of heart and coronary circulation
Groups that have been masked <i>No information</i>		Primary outcomes
Sample size Target sample size: 35		1 Description Fatigue Timepoint Baseline and 2, 4 and 6 hours after intervention Method of measurement Visual Analoge Scale for Fatigue
Randomization (investigator's opinion) Randomized		2 Description Pain Timepoint Baseline and 2, 4 and 6 hours after intervention Method of measurement Visual Analoge Scale for Pain
Randomization description		3 Description Blood pressure Timepoint
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 Faculty of Nursing and Midwifery , Tehran University of Medical Sciences Street address Faculty of Nursing and Midwifery, Tehran University of Medical Sciences , Nosrat St, Tohid Sq, Tehran, Iran City Tehran		

Baseline and 2, 4 and 6 hours after intervention
Method of measurement
Tytan Blood Pressure Devices

4

Description

Pulse

Timepoint

Baseline and 2, 4 and 6 hours after intervention

Method of measurement

According to minutes using the standard clock

5

Description

Breathing

Timepoint

Baseline and 2, 4 and 6 hours after intervention

Method of measurement

According to minutes using the standard clock

Secondary outcomes

empty

Intervention groups

1

Description

In reflexology group, massage is done by researcher and man collaborator(for male patients) for 10 minutes(5 minutes per foot). The sequence are used of relaxation and specific areas of the heart. Stages of relaxation include: Rhythmic ankle rotation(ankle rotation 4 time in the right and 4 times to the left to form the circle)and Wringing the foot(researcher thumbs are placed on the patient's abdominal area,then wringing the toe to the ankle,this work will be done 3 times) . After relaxation are used to stimulate the three areas of reflecting the solar plexus,heart,pituitary.the downward pressure are applied with the thumb in the heart,pituitary,solar plexus. then circular massage are applied the same points. With fatigue and pain VAS and physiologic parameters Questionnaire is recorded and assessed by collaborator , 2 hours after angiography, 2 and 4 hours after the procedure again.

Category

Other

2

Description

In the control group intervention will not occur, except routine care and vital signs measurement.fatigue ,pain and physiologic parameters Questionnaire recorded by collaborator and with presence of researcher at intervals corresponding reflexology group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah University of Medical Science

Full name of responsible person

Street address

MollaSadra St, Sheikh Bahai st, Tehran, Iran,
Baqiyatallah University of Medical Science

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Tehran University of
Medical Sciences

Full name of responsible person

Dr Akbar Fotoohi, Reasearch Vice chancellor, Tehran
University of Medical Sciences

Street address

Nosrat St, Tohid Sq, Tehran, Iran, Faculty of Nursing
and Midwifery, Tehran University of Medical Sciences

City

Tehran

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 Tehran 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

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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