Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effect of Foot Reflexology Massage, Foot Bath and Their Combination on Patient's Sleep Quality with Acute Coronary Syndrome

Protocol summary

Summary

The aim of this study is comparing the efficacy of three methods of foot reflexology massage, foot bath, and their combination on quality of sleep of hospitalized patients with Acute Coronary Syndrome . Inclusion criteria include : Patients with Acute Coronary Syndrome ؛ Alert patients؛ voluntary consent. Excluding criteria include: severe diabetic and neuropathy؛ Ejection Friction < 40%؛ Addiction to alcohol, Narcotic and Sedating Medication. The study population are patients with Acute Coronary Syndrome that Hospitalized in Baqiyatallah Hospital(Tehran , Iran in 2015). using random allocation sampling which dividing the patients into four groups of 35 members, including: foot reflexology massage group, foot baths group, combination group and control group(140 sample). In this study interventions are foot reflexology massage, foot bath, and their combination that done in second and third night of hospitalization , then changes in quality of sleep are surveyed and their results compared with control group. The first outcome of this study is improvement of quality of sleep in study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201603169521N3**
Registration date: **2016-05-11, 1395/02/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-11, 1395/02/22

Registrant information

Name

Ali Rahmani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Baqiyatallah University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effect of Foot Reflexology Massage, Foot Bath and Their Combination on Patient's Sleep Quality with Acute Coronary Syndrome

Public title

the Effect of Foot Reflexology Massage, Foot Bath on Patient's Sleep Quality with Acute Coronary Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :Patients with Acute Coronary Syndrome ; Alert patients;voluntary consent Excluding criteria include: severe diabetic and neuropathy; Ejection Friction < 40%; Addiction to alcohol, Narcotic and Sedating Medication

Age
From **18 years** old to **65 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Sciences, Mollasadra Street,Tehran, Iran
City
Tehran
Postal code
Approval date
2014-11-15, 1393/08/24
Ethics committee reference number
5904

Health conditions studied

1

Description of health condition studied
Acute Ischaemic Heart Diseases
ICD-10 code
I24.9
ICD-10 code description
Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description
quality of sleep
Timepoint
The second and third nights stay
Method of measurement
The sleep quality was measured by Veran Snyder-Halpern questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Group A (foot reflexology massage): In this group, rotational massage of solar plexus (Yang Quan area) perform in both feet of the patient (in the middle of the foot, between 1/3 and 2/3 of the inferior foot surface) for 10 minutes.
Category
Behavior

2

Description
Group C (combination): First, foot reflexology massage[rotational massage of solar plexus (Yang Quan area) perform in both feet of the patient (in the middle of the foot, between 1/3 and 2/3 of the inferior foot surface) for 10 minutes] and then foot bath[the patient sit in semi-sitting position with soaking the feet in 40°C water up to 10 cm above the ankle without washing or massage for 10 minutes] perform in each patient.
Category
Behavior

3

Description
Group B (foot bath): In this group, the patient sit in semi-sitting position with soaking the feet in 40°C water up to 10 cm above the ankle without washing or massage for 10 minutes
Category
Behavior

4

Description
Group D: Without any intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah University of Medical Sciences, Baqiyatallah Hospital
Full name of responsible person

Ali Rahmani

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Atherosclerosis Research Center, Baqiyatallah University

Full name of responsible person

Dr . Kazemi Saleh

Street address

Baqiyatallah Hospital, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Atherosclerosis Research Center, Baqiyatallah University

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

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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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