

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2245 6353

Email address

rahmani@bmsu.ac.ir

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
Baqiyatallah University of Medical Science

Full name of responsible person
Ali Rahmani

Position
Ph.D

Other areas of specialty/work

Street address
Baqiyatallah University of Medical Science , Faculty of
Nursing, Mollasadr Street, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 2245 6353

Fax

Email
rahmani@bmsu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Baqiyatallah University of Medical Science

Full name of responsible person
Ali Rahmani

Position
Ph.D

Other areas of specialty/work

Street address
Baqiyatallah University of Medical Science ,Mollasadra
Street, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 8862 0880

Fax

Email
rahmani@bmsu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Baqiyatallah University of Medical Science

Full name of responsible person
Ali Rahmani

Position

Other areas of specialty/work

Street address

City

Postal code

Phone
00

Fax

Email
rahmani@bmsu.ac.ir

Web page address

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