

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of hand and foot massage on anxiety and vital signs of patients with acute coronary syndrome.

Protocol summary

Summary

The purpose of this study is to investigate the effect of hand and foot massage on anxiety and vital signs of patients with acute coronary syndrome. Inclusion criteria: acute coronary syndrome; exclusion criteria: unwillingness to continue cooperation. The simple sampling will be done on eligible patients at second day of hospitalization. Before any act, the patient will be informed about keeping his/her information private, participating in the study voluntarily and the aims of the study. Then the written consent form will be completed by the patient. The patients will be randomly classified to one of the intervention(35 patient) or control groups(35 patient) by selecting one of two envelope(the name of "intervention group" is written and kept in one envelope the name of "control group" is written and kept in another). 30 minutes before the beginning of the intervention, the Spielberger's Anxiety Questionnaire will be completed and patients' vital signs will be checked and registered in vital signs checklist and also skin allergy test will be done for the intervention group. If the patient has no skin allergy, she/he will be provided with a 20-minute hand and foot massage (5 minutes to each extremity). We use stroking techniques and surface stroke. The vital signs of patients will be checked immediately after the intervention and 60 and 90 minutes after massaging. Then the patient will refill Spielberger's Anxiety Questionnaire 15 minutes after the massage therapy. In the control group, the vital signs will be checked as scheduled and then the Spielberger's Anxiety Questionnaire will be completed. The main outcome will be anxiety and vital signs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070134830N1**

Registration date: **2017-08-11, 1396/05/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-11, 1396/05/20

Registrant information

Name

Seyed Alimohammad Hasheminia

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 0061

Email address

hasheminiaali@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and technology affairs of Shahrekord University of Medical Sciences.

Expected recruitment start date

2017-07-06, 1396/04/15

Expected recruitment end date

2017-08-16, 1396/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hand and foot massage on anxiety and vital signs of patients with acute coronary syndrome.

Public title

The effect of massage on anxiety and vital signs.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 18 years; The patient is alert; specialist physician diagnosis of ACS; The patient should not have severe anxiety disorder; The patient is not being treated with warfarin; The patient should not have a pulse of less than 60 beats per minute or more than 110 beats per minute; In the last 72 hours there should be no respiratory interruption; The patient should not have a pacemaker; The patients should not have limb implantation; Lack of dangerous arrhythmias in the patient; The patient should not have coagulation disorders; The patient should not have history of bone fracture in the last two months; Patient should not have deep vein thrombosis; Patient should not have dialysis fistula in the upper limb; Not taking hypnotics, opiates, benzodiazepines and alcohol and spinal anesthesia by the patient within the last 4 hours; The patient should have a tendency to participate in the research project; Having healthy massage areas. Exclusion criteria: Unwillingness to continue cooperation

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study the samples are selected randomly using two envelopes. It is written in an envelope of the intervention group and inside the other control group, and the patient by selecting one of the envelopes divided in one of the two intervention or control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences, Kashani street, Shahrekord

City

Shahrekord

Postal code

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.SKUMS.REC.1396.83

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome.

ICD-10 code

I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

30 minutes before the intervention and 15 minutes after intervention.

Method of measurement

Spielberger's Anxiety Questionnaire.

2

Description

vital signs

Timepoint

30 minutes before the intervention, immediately after the intervention and 60 and 90 minutes after massaging.

Method of measurement

Blood pressure (pressure gauge) , pulse and respiration (by the researcher, in 1 min).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 30 minutes before the intervention the Spielberger's Anxiety Questionnaire will be completed and patients' vital signs will be checked and registered in vital signs checklist and skin allergy test will be done. If the patient had no skin allergy, she/he will be provided with a 20-minute massage on hand and foot (5 minutes to each extremity). We use stroking techniques and surface stroke for massaging. The vital signs of

patients will be checked 30 minutes before the intervention, immediately after the intervention and 60 and 90 minutes after massaging; then the patient refills Spielberger's Anxiety Questionnaire 15 minutes after the massage therapy.

Category

N/A

2

Description

In the control group, the vital signs will be checked as scheduled and then the Spielberger's Anxiety Questionnaire will be completed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar hospital

Full name of responsible person

Zahra Ghasemi

Street address

Hajar hospital, Parastar street, Shahrekord

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research of Shahrekord University of Medical Sciences

Full name of responsible person

Kamal Solati

Street address

Shahrekord University of Medical Sciences, Kashani street, Shahrekord

City

Shahrekord

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 of Shahrekord 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

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Zahra Ghasemi

Position

Msc student in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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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