

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of hand reflexology on pain, fatigue and hemodynamic parameters in patients after coronary cardiac catheterism

Protocol summary

Study aim

The effect of hand reflexology on pain, fatigue and hemodynamic parameters in patients after coronary cardiac catheterism

Design

Two arm parallel group randomised trial with blinded outcome assessment ,design on 90 patients,

Settings and conduct

The study is done at Rejaei Hospital in Karaj, Iran. The main investigator, data collector , data analytics are kept blind to allocation groups.

Participants/Inclusion and exclusion criteria

Company in the study; Age over 18 years old; Non-emergency coronary cardiac catheterism; Without having any previous history of coronary cardiac catheterism; The absence of vascular injuries of the upper limbs and sensory-motor disorders of the hands; The absence of abnormalities such as burns, amputations and skin disorders in the hands; The absence of inter-vertebral disc herniation, low back pain and back pain; Patients tend to benefit from mental health; Having full consciousness and able to communicate; Not having addiction to drugs and alcohol

Intervention groups

In reflexology group, 2 hours after coronary cardiac catheterism, massage is done for 20 minutes (10 minutes per hand). First, the whole palm is given the massage for 2 minutes. Then is stimulated the three areas of reflecting the solar plexus, heart, pituitary. The downward pressure is applied with the thumb in the heart, pituitary, solar plexus. then circular massage is applied the same points. Fatigue VAS, pain VAS, and hemodynamic parameters are recorded by the nurse, after intervention, 4 and 6 hours after the procedure again. In the control group, only routine care is done. The Fatigue VAS, pain VAS, and hemodynamic parameters are recorded by the nurse, at times consistent with the reflexology group.

Main outcome variables

fatigue; pain; hemodynamic parameters (pulse rate; respiratory rate; blood pressure)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N17**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of hand reflexology on pain, fatigue and hemodynamic parameters in patients after coronary cardiac catheterism

Public title
The effect of reflexology on patients after coronary cardiac catheterism

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients' willingness to participate in this study Age over 18 years old Non-emergency coronary cardiac catheterism Without having any previous history of coronary cardiac catheterism The absence of vascular injuries of the upper limbs and sensory-motor disorders of the hands The absence of abnormalities such as burns, amputations and skin disorders in the hands The absence of inter-vertebral disc herniation, low back pain and back pain The absence of any mental impairment Having full consciousness and able to communicate Not having addiction to drugs and alcohol
Exclusion criteria:
Patient's unwillingness to continue the collaboration in this study The patient's death Hemodynamic instability Bleeding after coronary cardiac catheterism

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Using of the Random blocks

Blinding (investigator's opinion)
Single blinded

Blinding description
The main investigator, data collector, data analytics are kept blind to allocation groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2017-10-30, 1396/08/08

Ethics committee reference number

IR.Shahed.REC.1396.52

Health conditions studied

1

Description of health condition studied

coronary cardiac catheterism

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

After intervention, 4 and 6 hours after coronary cardiac catheterism

Method of measurement

Visual Analogue Scale for Pain

2

Description

Fatigue

Timepoint

After intervention, 4 and 6 hours after coronary cardiac catheterism

Method of measurement

Visual Analogue Scale for Fatigue(Routen)

3

Description

Blood pressure

Timepoint

After intervention, 4 and 6 hours after coronary cardiac catheterism

Method of measurement

Sphygmomanometer

4

Description

Pulse rate

Timepoint

After intervention, 4 and 6 hours after coronary cardiac catheterism

Method of measurement

Watch

5

Description

Respiratory rate

Timepoint

After intervention, 4 and 6 hours after coronary cardiac catheterism

Method of measurement

Watch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In reflexology group, 2 hours after coronary cardiac catheterism, massage is done in the three areas of reflecting the solar plexus, heart, pituitary. Fatigue VAS, pain VAS, and hemodynamic parameters (pulse rate; respiratory rate; blood pressure) are recorded by the nurse, after intervention, 4 and 6 hours after the procedure again.

Category

Treatment - Other

2

Description

Control group: In the control group, only routine care is done. Fatigue VAS, pain VAS, and hemodynamic parameters (pulse rate; respiratory rate; blood pressure) are recorded by the nurse, at times consistent with the reflexology group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rejaei Hospital

Full name of responsible person

Fatemeh Rahimi

Street address

Martyr Rajaei Hospital, Martyr Rajaei Ave.

City

karaj

Province

Alborz

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34570030

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+98 26 3455 4484

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rajaei@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Vice chancellor for research, Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

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Kiasalari@shahed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Nahid Rejeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable