# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

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**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 Analoge Scale for Pain

### 2

**Description**

Fatigue

**Timepoint**

After intervention, 4 and 6 hours after coronary cardiac catheterism

**Method of measurement**

Visual Analoge 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.
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## 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
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## Person responsible for scientific inquiries

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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