

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing the effect of hand reflexology with foot reflexology on chest pain and anxiety in patients after primary coronary angioplasty.

#### Protocol summary

##### Study aim

Comparing the effect of hand reflexology with foot reflexology on chest pain and anxiety in patients after primary angioplasty.

##### Design

The randomized trial has two intervention groups and a control group using sealed envelopes for randomization on 114 patients.

##### Settings and conduct

Location: CCU department of Ayatollah Mousavi Zanjan Hospital. Foot reflexology: foot massage with massage oil, then reflexology with both thumbs from the center of the foot to the outside of the foot and finally massaging the center of the ball of the foot with the thumb. Hand reflexology: hand massage with massage oil, the soft area under the ring finger and little finger will be massaged 14 times in a row in a clockwise direction. In the control group, reflexology of the right foot will be performed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People who have undergone angiography for the first time; Age between 30 and 70 years; Transfemoral angiography; Normal pulse on the leg and posterior tibial pulse; Full consciousness. Exclusion criteria: Having a history of diabetes; Having addiction; People who received thrombolytic drugs (retplase) after MI and then underwent angiography 4) Any physiological or hemodynamic instability during and after angiography, such as cardiac dysrhythmia; Active bleeding at the catheter site.

##### Intervention groups

In this study, the samples will be divided into 3 groups: hand reflexology, foot reflexology and control group. In the control group, reflexology will be performed on the right foot of the patients.

##### Main outcome variables

Chest pain; anxiety

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230221057475N1**

Registration date: **2023-03-02, 1401/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-03-02, 1401/12/11**

Update count: **0**

##### Registration date

2023-03-02, 1401/12/11

##### Registrant information

##### Name

Sahar Asali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3378 6806

##### Email address

sasali075@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-01, 1401/12/10

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of hand reflexology with foot reflexology on chest pain and anxiety in patients after primary coronary angioplasty.

#### Public title

Investigating the effect of hand and foot reflexology on chest pain and anxiety in patients after primary coronary angioplasty

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

People who have been subjected to angioplasty for the first time Trans femoral angiography Having a pulse on the leg and a normal posterior tibial pulse Age between 30 and 70 years Having healthy hands and feet Full consciousness

##### Exclusion criteria:

Having a history of diabetes Having an addiction Having mental problems People who have received thrombolytic drugs (retplase) after MI and then underwent angiography. 5) Any physiological or hemodynamic instability during and after angiography, such as cardiac dysrhythmia. Active bleeding at the catheter site People who have already been subjected to angiography DVT history The presence of wounds, scars on the leg Use of anti-anxiety drugs Peripheral neuropathy Tickling feeling in hands and feet The presence of coagulation problems in the patient hypertension

#### Age

From **30 years** old to **70 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **114**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Allocating the samples to the study groups randomly, the random permutation block design with six blocks will be used; Then the website <https://www.sealedenvelope.com> will be used to determine the required random blocks and their sequence. Sealed envelopes will be used for concealment. Thus, based on the sequence of randomly determined blocks, cards with the letters A (for the hand reflexology group), B (for the foot reflexology group) and C (for the control group) will be placed inside the envelope, which shows the allocation sequence. became. Then an envelope will be opened for each participant in the study, and based on the card inside the envelope, the participant will be assigned to the control or test group.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

#### Secondary Ids

empty

#### Ethics committees

##### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

###### Street address

No.1154, West second Eshragh Ave., Shahryar Town

###### City

Zanjan

###### Province

Zanjan

###### Postal code

4515917897

##### Approval date

2023-02-14, 1401/11/25

##### Ethics committee reference number

IR.ZUMS.REC.1401.348

#### Health conditions studied

##### 1

##### Description of health condition studied

acute myocardial infraction

##### ICD-10 code

I21

##### ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

#### Primary outcomes

##### 1

##### Description

chest pain

##### Timepoint

Before the start of the intervention, 15 minutes, 3 hours and 6 hours after the end of the intervention

##### Method of measurement

Visual Analogue Scale

##### 2

##### Description

Anxiety

##### Timepoint

Before the start of the intervention, 15 minutes, 3 hours and 6 hours after the end of the intervention

##### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The patient lies on the bed in a quiet environment. We place a pillow under the patient's feet, after removing the ornaments and washing the hands, the masseur begins to perform the intervention. Foot reflexology is performed on the patient's left foot for 15 minutes. Massage oil, which has no therapeutic value, is used to perform reflexology. Pressure will be applied for 30 seconds with the tip of the thumb to the center of the sole of the foot at the point of the solar plexus at the junction of the ball of the foot and the arch of the foot. Reflexology will be done with a circular movement with both thumbs from the center of the foot to the outside of the foot. Finally, the heart area (the center of the ball of the foot) will be massaged with the thumb in one movement.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: The patient lies on the bed in a quiet environment. After removing the jewelry and washing the hands, the masseuse starts to perform the intervention. Hand reflexology is performed on the patient's left hand for 15 minutes. To perform reflexology, massage oil is used, which has no therapeutic value. To perform hand reflexology, the researcher will start massaging the hand from the sides of the hand and move towards the palm, the back of the hand, and finally the fingers. This process will be repeated eight to ten times until the hand is completely relaxed and ready for reflexology. The reflex point for the cardiovascular system includes: the heart point located on the palm, under the soft area at the bottom of the ring and little fingers, the massager will press the reflexology point with his thumb. Reflexology points will be massaged 14 times in a row clockwise and with circular movements.

#### Category

Treatment - Other

### 3

#### Description

Control group: The patient lies on the bed in a quiet environment, we place a pillow under the patient's feet, after removing the ornaments and washing the hands, the masseuse begins to perform the intervention. Foot reflexology is performed on the patient's right foot for 15 minutes. Massage oil, which has no therapeutic value, is used to perform reflexology. Pressure will be applied for 30 seconds with the tip of the thumb to the center of the sole of the foot at the point of the solar plexus at the

junction of the ball of the foot and the arch of the foot. Reflexology will be done with a circular movement with both thumbs from the center of the foot to the outside of the foot. Finally, the heart area (the center of the ball of the foot) will be massaged with the thumb in one movement.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Mousavi Zanjan Hospital

##### Full name of responsible person

Sahar Asali

##### Street address

Gavazang Street., Zanjan

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4513956183

##### Phone

+98 24 3313 0000

##### Fax

+98 24 3313 1203

##### Email

Mousavihospital@zums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr. Hossein Mostafavi

##### Street address

Mahdavi Blvd, Zanjan University of Medical Sciences

##### City

Zanjan

##### Province

Zanjan

##### Postal code

4515613191

##### Phone

+98 24 3315 6394

##### Fax

+98 24 3342 4770

##### Email

vakili@zums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

**Title of funding source**

Zanjan University of Medical Sciences

**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

Zanjan

**Province**

Zanjan

**Postal code**

4513956113

**Phone**

+98 24 3314 8318

**Email**

sasali075@gmail.com

**Person responsible for general inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Sahar Asali

**Position**

Master student of emergency nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifer Zanjan, Mahdavi Blvd., Karmandan Town,Zanjan

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956113

**Phone**

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sasali075@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Sahar Asali

**Position**

Master student of emergency nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

School of Nursing and Midwifery,Mahdavi Blvd, Karmandan Town

**City****Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Sahar Asali

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**Email**

sasali075@gmail.com

**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**

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

**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**

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

**Data Dictionary**

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