# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The Comparison between of foot and hand reflexology on anxiety in patients with angiography candidates

## Protocol summary

**Summary**

The aim of this study was to compare the effects of posted shortly feet reflexology massage and hands reflexology massage on anxiety patients undergoing coronary angiography. In this randomized clinical trial, 135 candidates of angiography were randomly allocated to three groups (first week for foot reflexology, second week for hand reflexology massage, third week for control group and again this random allocation is repeated) into experimental and control groups (35 patients in each group). The study will be conducted on female patients candidates for angiography in patients admitted to Kosar hospital in Semnan. Sampling begins after explaining the objectives of the study and obtaining informed consent from patients in different groups. In the foot and hand reflexology massage groups, patients were placed in a comfortable position and either feet or hands are messaged for ten minutes. Spielberger standard questionnaire and hemodynamic parameters will be gathered before and after intervention, and one minute after angiography. The control group will not receive any type of intervention and only anxiety and hemodynamic parameters will be measured after twenty minutes interval. The researchers and data monitoring committee will not become aware of what sort of intervention the patients have been received.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201412087529N6**
Registration date: **2015-01-16, 1393/10/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-01-16, 1393/10/26

**Registrant information**

**Name**
Nahid Rejeh
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**Recruitment status**

**Recruitment complete**

**Funding source**

Shahed University Vice chancellor for research

**Expected recruitment start date**

2014-10-14, 1393/07/22

**Expected recruitment end date**

2015-01-10, 1393/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Comparison between of foot and hand reflexology on anxiety in patients with angiography candidates

**Public title**

Effect of massage on the level of anxiety

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

nclusion criteria: the desire to participate in the study; having no previous history of angiography; having no order of emergency angiography; having 20 number

anxiety; age over 18 years old;; health in the legs and hands; patients not taking the narcotic drug alcohol, ; having no previous history of mental disorder; not using anticoagulation medications; No diabetes; Do not have the risk of deep vein thrombosis. Exclusion criteria: injury or infection at the site of reflex zone therapy; anxiolytic or hypnotic drugs in the 8 hours before reflex zone therapy; condition of hemodynamic is unstable; transfer of patient to intensive care unit and cardiopulmonary resuscitation of the patient.

**Age**
From **18 years** old to **80 years** old

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **135**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
The patients are randomly allocated in to the three study groups: foot reflexology massage, hand reflexology massage and control group (35 patients in each group). Random allocated to intervention and control groups, assign patients were given this manner: (first week for foot reflexology, second week for hand reflexology massage, third week for control group and again this random allocation is repeated )The researchers and data monitoring committee will not become aware of what sort of intervention the patients receive.

## 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 Express way , Tehran ,Iran

**City**
Tehran

**Postal code**

**Approval date**
2014-09-09, 1393/06/18

**Ethics committee reference number**
4/629

## Health conditions studied

### 1

**Description of health condition studied**
Anxiety in patients with angiographic candidates

**ICD-10 code**
F40-48

**ICD-10 code description**
Neurotic, stress-related and somatoform disorders

## Primary outcomes

### 1

**Description**
satisfaction

**Timepoint**
30 minutes after angiography

**Method of measurement**
satisfaction Visual Analog Scale

### 2

**Description**
Anxiety

**Timepoint**
Before intervention , one minute after intervention, and one minute after angiography

**Method of measurement**
Spielberger questionnaire

### 3

**Description**
Blood pressure

**Timepoint**
Before intervention , one minute after intervention, and one minute after angiography

**Method of measurement**
phygmomanometer

### 4

**Description**
Respiratory rate

**Timepoint**
Before intervention , one minute after intervention, and one minute after angiography

**Method of measurement**
Checklist

### 5

**Description**
Pulse rate

**Timepoint**
Before intervention , one minute after intervention, and one minute after angiography

**Method of measurement**

Checklist

**6**

**Description**
Oxygen saturation
**Timepoint**
Before intervention , one minute after intervention, and one minute after angiography
**Method of measurement**
pulse oximeter

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
In foot reflexology massage group is done 20 minutes.(10 minutes for per foot). massage techniques on reflex points of the pituitary, spinal cord and solar plexus .reflection of the pituitary is in inner edge of middle portion in the first Knucklebone of the big in plantar plantar, solar plexus is in end of the first metatarsal bone in foot and reflection of the spinal cord is in the inner edge of the foot, starting from the end of the first Knucklebone of the thumb and leads to heel. The level of anxiety (measured by using spielburger questionnaire) and hemodynamic parameters (recorded in a checklist) are used before intervention , one minute after intervention, and one minute after angiography
**Category**
Other

**2**

**Description**
In hand reflexology massage group is done 20 minutes.(10 minutes for per hand).In the hand Reflexology group for the points massage, including the pituitary gland and solar plexus is performed. The level of anxiety (measured by using spielburger questionnaire) and hemodynamic parameters (recorded in a checklist) are used before and after intervention, while and after angiography
**Category**
Treatment - Other

**3**

**Description**
control group without any intervention
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kosar hospital in Semnan university of medical sciences
**Full name of responsible person**
Dr.Kamran Godus
**Street address**
Semnan university of medical sciences;Golestan street;Semnan;Iran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahed University Vice chancellor for research
**Full name of responsible person**
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Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way , Tehran ,Iran
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Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahed University Vice chancellor for research
**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

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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*