

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Sep 2026

### Effect of foot reflexology on anxiety rate and vital signs before coronary angiography in males hospitalized in coronary care unit

#### Protocol summary

##### Summary

After learning "foot Reflexology technique", one day before angiography test, the researcher goes to Cardiology and CCU wards of Hospital and selects his candidates according to inclusion and exclusion criteria. Then he divides the study groups in odd or even. Number of samples in each group are 50. Inclusion criteria contain: Male patients hospitalized in CCU ; Being conscious; Willing to participate. Exclusion criteria contain: No willing to continue the study. Anxiety rate is determined by Spielberger questionnaire. Then anxiety rate and vital signs are determined and compared between 2 groups before and after the study. The technique is done as described below: the researcher washes his hands with warm water and then uses a softening oil (without any therapeutic effect) that only facilitate the massage (like sunflower oil). Massage starts from left foot in 3 points contained sensitive solar network, hypophysis and heart. These points are pressed constantly for 2 minutes and then they are massaged in a circle manner. Thirty minutes after doing technique, vital signs will be checked and anxiety Spielberger questionnaire will be completed again. Reflexology can be done only once before angiography. Vital signs determine by a mercury Sphygmomanometer (alkp2-Japan) and a digital watch Casio Japanese N1df model. blood pressure will be measured by a mercury Sphygmomanometer. Heart and respiratory rate will be measured by a digital clock.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012082710677N1**

Registration date: **2012-12-14, 1391/09/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-12-14, 1391/09/24

##### Registrant information

###### Name

Mehdi Molavi Vardanjani

###### Name of organization / entity

Kashan University of Medical Sciences, Kashan

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0366

###### Email address

mehdi.molavi@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research Kashan University of Medical Sciences

##### Expected recruitment start date

2012-12-21, 1391/10/01

##### Expected recruitment end date

2013-05-22, 1392/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of foot reflexology on anxiety rate and vital signs before coronary angiography in males hospitalized in coronary care unit

##### Public title

Effect of foot reflexology on anxiety rate

##### Purpose

Treatment

**Inclusion/Exclusion criteria**  
 Inclusion criteria: Male patients hospitalized in CCU ;  
 Being conscious; Willing to participate; Not using  
 anticoagulation medications; No diabetes; Do not have  
 the risk of deep vein thrombosis; No drug addiction;  
 Without any history of psychologic problems or strong  
 anxiety personality; Not being an emergency  
 angiography case; Not taking anti-anxiety medication in  
 the past 48 hours. Exclusion criteria: Not having the  
 ability or willing to continue the study.

**Age**  
 From **18 years** old to **65 years** old

**Gender**  
 Male

**Phase**  
 2

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

**Sample size**  
 Target sample size: **100**

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

**Randomization description**

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

**Blinding description**

**Placebo**  
 Not used

**Assignment**  
 Single

**Other design features**  
 Simple random sampling is based on a coin toss. The  
 samples are placed in two groups, odd and even.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kashan University of Medical  
 Sciences

##### Street address

5th km Ghotb Ravandi, Kashan University of Medical  
 Sciences, Kashan

##### City

Kashan

##### Postal code

88141/87159

##### Approval date

2012-06-08, 1391/03/19

##### Ethics committee reference number

1607/1/5/29/ب

## Health conditions studied

### 1

#### Description of health condition studied

Angina pectoris

#### ICD-10 code

120.0

#### ICD-10 code description

Angina pectoris

## Primary outcomes

### 1

#### Description

blood pressure

#### Timepoint

Before and 30 minutes after reflexology

#### Method of measurement

Sphygmomanometer

### 2

#### Description

Heart rate

#### Timepoint

Before and 30 minutes after reflexology

#### Method of measurement

Digital watch

### 3

#### Description

anxiety

#### Timepoint

before and 30 minutes after reflexology

#### Method of measurement

Spielberger questionnaire

### 4

#### Description

Respiratory rate

#### Timepoint

Before and 30 minutes after reflexology

#### Method of measurement

digital watch

## Secondary outcomes

### 1

#### Description

marital

#### Timepoint

before intervention

#### Method of measurement

married- single

### 2

#### Description

type of angiography

#### Timepoint

before intervention  
**Method of measurement**  
Therapeutic-Diagnostic

### 3

#### **Description**

age

#### **Timepoint**

before intervention

#### **Method of measurement**

years

## **Intervention groups**

### 1

#### **Description**

group 1: Reflexology will be done one hour before angiography and vital signs and anxiety rate will be checked 30 minutes before and after reflexology. Then Spielberger questionnaire will be filled.

#### **Category**

Treatment - Other

### 2

#### **Description**

group 2 : Foot massage will be done 1 hour before angiography and vital signs and anxiety rate will be checked 30 minutes before and after massage. Then Spielberger questionnaire will be filled.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Beheshti Hospital of Kashan

##### **Full name of responsible person**

Mehdi Molavi Vardanjani

##### **Street address**

5th km Ghotb Ravandi, Kashan University of Medical Sciences, Beheshti Hospital, Kashan

##### **City**

Kashan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research Kashan University of Medical Sciences

##### **Full name of responsible person**

Gholam Ali Hamidi

##### **Street address**

5th km Ghotb Ravandi, Kashan University of Medical

Sciences, Kashan

##### **City**

Kashan

##### **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 Kashan 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**

5th km Ghotb Ravandi, Kashan University of Medical Sciences, Kashan

##### **Full name of responsible person**

Mehdi Molavi Vardanjani

##### **Position**

Master of Science

##### **Other areas of specialty/work**

##### **Street address**

Kashan, 5th km Ghotb Ravandi, Kashan University of Medical Sciences, Kashan

##### **City**

Kashan

##### **Postal code**

87159/88141

##### **Phone**

+98 36 1555 0366

##### **Fax**

-----

##### **Email**

mehdi.molavi@kaums.ac.ir

##### **Web page address**

ندارد

## **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

5th km Ghotb Ravandi, Kashan University of Medical Sciences, Kashan

##### **Full name of responsible person**

Masoudi Negin

##### **Position**

PHD

##### **Other areas of specialty/work**

**Street address**

Kashan, 5th km Ghotb Ravandi, Kashan University of  
Medical Sciences, Kashan

**City**

Kashan

**Postal code**

87159/88141

**Phone**

+98 36 1555 0366

**Fax**

ندارد

**Email**

alavi.negin@yahoo.com

**Web page address**

www.kaums.ac.ir

Medical Sciences, Kashan

**City**

Kashan

**Postal code**

87159/88141

**Phone**

+98 36 1555 0366

**Fax**

-----

**Email**

mehdi.molavi@kaums.ac.ir

**Web page address**

www.kaums.ac.ir

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

5th km Ghotb Ravandi, Kashan University of Medical  
Sciences, Kashan

**Full name of responsible person**

Mehdi Molavi Vardanjani

**Position**

Master of Science

**Other areas of specialty/work****Street address**

Kashan, 5th km Ghotb Ravandi, Kashan University of

**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*