

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