

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Assessment of effects of foot-bath on anxiety and physiologic parameters of patients undergoing coronary angiography at Koosar hospital in Semnan

Protocol summary

Summary

The aim of this study is assessment of effects of foot-bath on anxiety and physiologic parameters of patients undergoing coronary angiography in Koosar hospital of Semnan. Inclusion criteria include admission for coronary angiography for the first time, having literacy above the sixth grade and hemodynamic stability. Exclusion criteria include history of drug abuse, history of psychiatric disorders, previous use of Foot-bath device, ulceration and contagious skin diseases in the lower extremities and dangerous arrhythmias during the intervention. The study population are patients referred for coronary angiography and the samples consist of 92 patients that assigned in two intervention and control group randomly. Intervention group at first complete Spielberger anxiety scale and physiologic parameters were be taken with same instruments. Then foot -bath with Foot-bath device is done for 10 minutes. Then patients complete the Spielberger anxiety scale and physiological parameters will be checked and recorded again. Control group at first complete Spielberger Anxiety Scale and physiological parameters were be taken with same instruments. Then they rest in bed for 10 minutes and finally complete the Spielberger anxiety scale and physiological parameters will be checked and recorded again. The primary outcome of this study is patient anxiety and secondary outcomes are blood pressure, pulse rate and o2 saturation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072118550N1**

Registration date: **2014-09-29, 1393/07/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Chancellor for research of Semnan University of Medical Sciences

Expected recruitment start date

2014-11-07, 1393/08/16

Expected recruitment end date

2015-07-07, 1394/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effects of foot-bath on anxiety and physiologic parameters of patients undergoing coronary angiography at Koosar hospital in Semnan

Public title

Effect of foot-bath on anxiety

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Admission for coronary intervention for the first time, Having full consciousness and awareness of time and place, Having literacy level above 6 grade of Hemodynamic stability, Receiving the last dose of the drug 4 hour before completing questionnaire and receiving sedatives the night before the day of angiography , Willingness to participate in research, exclusion criteria: Narcotic addiction, Having previously known mental disorder, History of using foot bath instrument, Interrupting or non complete intervention (due to patient noncompliance or dangerous Cardiac arrhythmia), Having cancer, lupus, skin diseases, ulcers in the intervention site (the middle leg to the tip of the toes) , Having a contagious skin disease in the lower limbs Patients is relatives or acquaintances of medical personnel

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 92

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Chancellor for research of Semnan University of Medical Sciences, Boulevard Jahad, Semnan,Iran

City

Semnan

Postal code

38118-35131

Approval date

2014-08-30, 1393/06/08
Ethics committee reference number
93/490113

Health conditions studied

1

Description of health condition studied

Coronary artery angiography

ICD-10 code

I79 ,I78,

ICD-10 code description

Disorders of arteries, arterioles and capillaries in diseases classified elsewhere

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention, immediately after intervention and 30 minute after intervention

Method of measurement

with using standard Spielberger Anxiety Scale

Secondary outcomes

1

Description

Physiological parameter

Timepoint

before intervention, immediately after intervention and 30 minutes after intervention

Method of measurement

Tympanic thermometer, Digital sphygmomanometer, Pulse-oximeter and counting respiratory rate

Intervention groups

1

Description

"Intervension group: Putting two foot of patients for 10 minutes in Foot-bath device"

Category

Other

2

Description

"Control group: Do not recieve any intervention"

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Koosar Hospital of Semnan

Full name of responsible person

Nayyereh Raiesdana

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Faculty of Nursing and Allied Health, Semnan
University of Medical Sciences, 5th kilometer of
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Chancellor for research of Semnan University of
Medical Sciences

Full name of responsible person

Dr Ali Rashidipoor

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Chancellor for research of Semnan University of
Medical Sciences, Boulevard Jahad, Semnan, Iran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Chancellor for research of Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Phd-Assistant professor

Other areas of specialty/work

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Web page address

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