Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Citrus Aurantium Aroma and Acupressure on sleep quality in patients undergoing percutaneous coronary intervention (PCI)

Protocol summary

Summary

This study aimed to compare Citrus Aurantium Aroma and Acupressure on sleep quality in patients undergoing percutaneous coronary intervention (PCI). In this controlled randomized clinical trial, a sample of 75 patients under PCI in the heart unit of the Fatemeh Al Zahra hospital in Sari will select by convenience sampling and randomly divided into five groups (Aromatherapry, Placebo of aroma, acupressure, placebo of acupressure and control). Inclusion Criteria: Diagnosis of acute myocardial infarction or angina pectoris requiring PCI; Non-use of herbal medicines in the past two weeks; Not having a history of sleep disorders in a recent month; No- narcotic drug use; no scars at the Shenmen point; Non-use sleep medication during the past month; no history of acupressure; lack of olfactory impairment; patients who are first placed under PCI. Exclusion Criteria: Patient's unwillingness to cooperate or death; History of respiratory disorders or allergies to plants; Carpal tunnel syndrome; BMI> 35. The night before the coronary intervention, the demographic information and Spielberger's anxiety questionnaire will be completed by the patients. Patients will be treated with random blocks in one of the test, placebo, or control groups, and aromatherapy and acupressure interventions will be performed at 10 o'clock in the afternoon for 10 hours, and the next morning, the sleep quality of the patient last night using the SMHSQ will be completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707248665N6**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

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Hassan Babamohamadi
Name of organization / entity
Semnan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Citrus Aurantium Aroma and Acupressure on sleep quality in patients undergoing percutaneous coronary intervention (PCI)

Public title

Comparison of Citrus Aurantium Aroma and Acupressure on sleep quality in patients undergoing percutaneous coronary intervention (PCI)

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion Criteria: Age range 40-75 years; Diagnosis of acute myocardial infarction or angina pectoris requiring PCI; Non-use of herbal medicines in the past two weeks; Not having a history of sleep disorders in a recent month; No- narcotic drug use; no scars at the Shenmen point; Non-use sleep medication during the past month; no history of acupressure; lack of olfactory impairment; patients who are first placed under PCI. Exclusion Criteria: Patient's unwillingness to cooperate or death; History of respiratory disorders or allergies to plants; Carpal tunnel syndrome; BMI> 35.
Age
From **40 years** old to **75 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
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
Semnan University of Medical Sciences
Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran
City
Semnan
Postal code
3519899951
Approval date
2017-07-12, 1396/04/21
Ethics committee reference number
IR.SEMUMS.REC.1396.64

Health conditions studied

1

Description of health condition studied
Heart disease
ICD-10 code
I20-I25
ICD-10 code description
Ischemic Heart Disease

Primary outcomes

1

Description
Sleep Quality
Timepoint
At the end of study
Method of measurement
St Marry’s Hospital Sleep questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In the first group (Citrus Aurantium Aroma) after getting informed consent, they will complete demographic and spielberger questionnaires at 10 o'clock. Cotton is stained with 2 drops of Citrus Aurantium put in front of the patient's nose and patients are asked to do 2-3 deep breathing. The cotton ball is then attached to patient's shirt using a pin and until 8am. Then the cotton bullet will be separated from the patient's clothing and will be discarded, and the sleep quality of the night will be checked by using SMHSQ.
Category
Other

2

Description
In the second group (placebo aroma) after getting informed consent, they will complete demographic and Spielberger questionnaire at 10 o'clock. Cotton is stained with 2 drops of sunflower oil put in front of the patient's nose and patients are asked to do 2-3 deep breathing. The cotton ball is then attached to patient's shirt using a pin and until 8am. Then the cotton bullet will be separated from the patient's clothing and will be discarded, and the sleep quality of the night will be checked by using SMHSQ.
Category
Other

3

Description
In the third group (Accupressure) after getting informed consent, they will complete demographic and spielberger questionnaires at 10 o'clock. The wristband, which has a metal button with a diameter of 0.7 cm, is closed for 1 night on both the right and left wrists of the patient so that the metal button is placed on the point of intervention (Shenmen). The pressure is applied to a patient who does not feel the pain and discomfort of the wrist strap. The sleep quality of the night will be checked by using SMHSQ.

Category
Other

4

Description
In the fourth group (Placebo of accupressure) after getting informed consent, they will complete demographic and spielberger questionnaires at 10 o'clock. The wristband on both the right and left wrists of the patient will be closed so that the metal button is located 1-1/5 cm from the point of Shenmen (false point). The seaband is closed on the wrists for 1 night. The sleep quality of the night will be checked by using SMHSQ.

Category
Other

5

Description
In the fifth group (Control) after getting informed consent in control group, they will complete demographic and spielberger questionnaires at 10 o'clock. they will receive only routine nursing care. The sleep quality of the night will be checked by using SMHSQ.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Al Zahra Hospital, Sari

Full name of responsible person

Street address

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr Ali Rashidypour

Street address
Vice Chancellor of Research and Technology, Semnan University of Medical Sciences, Basidj Blv, Semnan, Iran

City
Semnan

Grant name

Grant code / Reference number

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

Title of funding source
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
Hassan Babamohamadi

Position
Associate Professor

Other areas of specialty/work

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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