Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of aromatherapy with lavender extract on sleep quality in hospitalized patient candidate for angiography

Protocol summary

Study aim
Determination of the effect of Aromatherapy with lavender extract on sleep quality of patients candidate for Angiography admitted to the coronary care unit of Ali Ebn Abitaleb Hospital in Rafsanjan

Design
randomized control trial with two control and intervention group

Settings and conduct
The research population of this study is all of the patients candidate for angiography admitted to the coronary care unit . Samples are selected by available method and then categorized randomly in each of the two groups.

Participants/Inclusion and exclusion criteria
inclusion criteria: 40-60 years old; confirmation of acute coronary syndrome by cardiologist; willingness of patient; absence of confirmed mental disorder; absence of history of asthma; Not having a history of allergy to plants or any seasonal; allergies absence of olfactory disorder; absence of severe pain causing sleep disorder; Their sleep quality score is at least 22; At least 24 hours after admission to the CCU; No entry criteria : absence of cooperation or patient satisfaction; No mechanical ventilation; Lack of life-threatening complications;

Intervention groups
Then, patients complete the St. Mary's Sleep Quality Questionnaire. In the intervention group, impregnated cotton napkin with 15 drops of lavender essential oil made by Barij Essence Company and pinned it to the pillow of the patient and wound up in the morning after waking up.In the control group, we put cotton napkin into 15 drops of water and put it in the pillow of the patient. The next morning, the questionnaires were again filled up by the patients and the data were collected.

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180919041067N1**
Registration date: **2019-04-07, 1398/01/18**
Registration timing: **retrospective**

Last update: **2019-04-07, 1398/01/18**
Update count: **0**

Registration date
2019-04-07, 1398/01/18

Registrant information

Name
najmeh Mohammadrafie

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3426 9486

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-21, 1397/04/30

Expected recruitment end date
2018-11-21, 1397/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of aromatherapy with lavender extract on sleep quality in hospitalized patient candidate for angiography

Public title

Investigating the effect of aromatherapy with lavender extract on sleep quality in hospitalized patient candidate for angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 40 to 60 years Acute coronary syndrome confirmed by cardiologist willingness to participate in the study no history of mental disorders no history of asthma no history of allergy to plants or any seasonal allergy no history of olfactory disorders lack of severe pain that causes sleep disturbance sleep quality score of at least 22 a minimum of 24 hours of admission to the cardiac care unit

Exclusion criteria:

Patient dissatisfaction no need for mechanical ventilation life-threatening complications such as Cardiopulmonary resuscitation

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected by convenience method and then categorized randomly into each of the two groups. In this method, the first samples are randomly In this method, the first samples are randomly assigned to one of the groups, and for subsequent samples, the number of samples in each of the groups is considered, and the sample is assigned to a group that is less.assigned to one of the groups and for subsequent samples the number of samples in each group is considered and the sample belongs to a group that is less.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are randomly assigned to the intervention and control group and do not have any knowledge of the presence of any of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd (Central Office of Rafsanjan University of Medical Sciences)

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-04-20, 1397/01/31

Ethics committee reference number

IR.RUMS.REC.1397.025

Health conditions studied

1

Description of health condition studied

Chronic ischemic heart disease

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

2

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Patients' sleep quality score

Timepoint

Scoring the sleep quality questionnaire in two consecutive nights before intervention and after intervention

Method of measurement

St. Mary's Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The night before angiography, we impregnate cotton napkin with 15 drops of lavender 20 % and pin it to the pillow of the patient and take it in the morning after waking up.
Category
Other

2

Description
Control group: The night before angiography, we impregnate cotton napkin with 15 drops of water and pin it to the pillow of the patient and take it in the morning after waking up.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Aliebn Abitaleb hospital-Moffateh Blvd-rafsanjan
Full name of responsible person
Ahmadraza Sayadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ahmadreza Sayadi
Position
Assistant Professor, Faculty of Nursing and Midwifery, Rafsanjan
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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available