

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

Phone

+98 34 3426 9486

Email address

mohammadrafien@yahoo.com

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		Secondary Ids empty
Public title Investigating the effect of aromatherapy with lavender extract on sleep quality in hospitalized patient candidate for angiography		Ethics committees
Purpose Supportive		<u>1</u>
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		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
Age From 40 years old to 60 years old		Approval date 2018-04-20, 1397/01/31
Gender Both		Ethics committee reference number IR.RUMS.REC.1397.025
Phase N/A		Health conditions studied
Groups that have been masked Participant		<u>1</u> Description of health condition studied Chronic ischemic heart disease ICD-10 code I25 ICD-10 code description Chronic ischemic heart disease
Sample size Target sample size: 75		<u>2</u> 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
Randomization (investigator's opinion) Randomized		Primary outcomes
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.		<u>1</u> 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
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 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

Street address

Aliebn Abitaleb hospital-Moffateh Blvd-rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0000

Email

aliebn@rums.ac.ir

Web page address

https://rums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ahmadraza Sayadi

Street address

Ali_ebn Abitaleb hospital_Moffateh Blvd_rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Fax

+98 34 3428 0071

Email

info@rums.ac.ir

Web page address

https://rums.ac.ir

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

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery faculty/nursing avenue (coastal) Motahari Ave Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Phone

+98 34 3425 5900

Email

parastari@rums.ac.ir

Web page address

https://nm.rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ahmadraza Sayadi

Position

Associate Professor of the Faculty of Nursing,
Midwifery and Allied Medical Sciences of Rafsanjan

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Rafsanjan Motahari Ave nursing avenue (coastal)
nursing and midwifery faculty

City

Rafsanjan

Province

Kerman

Postal code

7718796755

Phone

+94 3434255900

Email

Sayadiahmad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Najmeh Mohammadrafie

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 17- Alley # 1, Shariati St.,Rafsanjan,

City

Rafsanjan

Province

Kermanshah

Postal code

7715714557

Phone

+98 34 3426 9486

Email

Mohammadrafien@yahoo.com

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