

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of Inhalation Aromatherapy with Citrus Aurantium and lavender on Sleep Quality, and Symptoms of Anxiety and Depression among Acute Coronary Syndrome Patients: A Parallel Randomized Controlled Trial

Protocol summary

Study aim

Comparison of the effect of inhalation aromatherapy with citrus aurantium and lavender on sleep quality, and symptoms of anxiety and depression among acute coronary syndrome patients

Design

A phase III parallel randomized clinical trial, 3 groups (2 interventions and 1 control group); phase 3, uses a random blocking allocation that cannot be blinded and a sample size will be 90 people.

Settings and conduct

The setting of study is Imam Hossein Hospital in Shahrud. The study is held for three consecutive nights. The standard questionnaires of the hospital anxiety and depression and hospital quality of sleep are completed by all three groups before the intervention and then on the morning of the fourth day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definitive diagnosis of acute coronary syndrome by a specialist, Full consciousness (GCS=15), The patient has been admitted to the hospital 24-48 hours before the intervention. Exclusion criteria: Acute psychological disorders, Neuroleptic medication, Opioid drug consumption 6 hours before the intervention, Allergy to plants and their scent, Lack of sense of smell.

Intervention groups

In aromatherapy groups with lavender and citrus aurantium essential oil, every night for three consecutive nights, 5 drops of lavender and citrus aurantium essential oil will be poured on a piece of cotton and placed under the outer cover of the patient's pillow at a distance of about 20 cm from the nose. The cotton pad remains in place for 8 hours (10:00 PM to 6:00 AM). In the control group, distilled water will be used as a placebo.

Main outcome variables

Anxiety, depression and sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180728040617N8**

Registration date: **2023-06-28, 1402/04/07**

Registration timing: **prospective**

Last update: **2023-06-28, 1402/04/07**

Update count: **0**

Registration date

2023-06-28, 1402/04/07

Registrant information

Name

Seyedmohammad Mirhosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 3811

Email address

mirhoseinim@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-10-07, 1402/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Inhalation Aromatherapy with Citrus Aurantium and lavender on Sleep Quality, and Symptoms of Anxiety and Depression among Acute Coronary Syndrome Patients: A Parallel Randomized Controlled Trial

Public title

Comparison of the effect of Inhalation Aromatherapy with Citrus Aurantium and lavender on Sleep Quality, and Symptoms of Anxiety and Depression among Acute Coronary Syndrome Patients: A Parallel Randomized Controlled Trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of acute coronary syndrome by a specialist Full consciousness (GCS=15) The patient has been admitted to the hospital 24-48 hours before the intervention.

Exclusion criteria:

Acute psychological disorders Neuroleptic medication
Opioid drug consumption 6 hours before the intervention
Allergy to plants and their scent Lack of sense of smell

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into three aromatherapy groups with lavender, citrus aurantium and control by random block allocation using six blocks created by SPSS software. According to the sample size of 90 people in the present study, 15 blocks of six will be considered. Each patient will be randomly assigned to lavender aromatherapy group (A), citrus aurantium aromatherapy (B) and control group (C) based on the order determined by the software. The sampling process will be done sequentially until the sampling is completed. People are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.SHMU.REC.1402.041

Health conditions studied**1****Description of health condition studied**

acute coronary syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes**1****Description**

Anxiety: Anxiety refers to the score that can be obtained from the Sigmund Anxiety and Depression Hospital Scale.

Timepoint

before the intervention and 3 nights after the intervention (the morning of the fourth day)

Method of measurement

Sigmunds' Hospital Anxiety and Depression Scale

2**Description**

Depression: Depression refers to the score that can be obtained from the Sigmund Anxiety and Depression Hospital Scale.

Timepoint

Before the intervention and 3 nights after the intervention (the morning of the fourth day).

Method of measurement

Sigmunds' Hospital Anxiety and Depression Scale

3

Description

Sleep quality: Sleep quality refers to the score that can be obtained from the St. Mary's Hospital Sleep Quality Questionnaire.

Timepoint

Before the intervention and 3 nights after the intervention (the morning of the fourth day)

Method of measurement

St. Mary's Hospital Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In aromatherapy groups with lavender essential oil, every night for three consecutive nights, 5 drops of lavender essential oil will be poured on a piece of cotton and placed under the outer cover of the patient's pillow at a distance of about 20 cm from the nose. The cotton pad remains in place for 8 hours (10:00 PM to 6:00 AM).

Category

Other

2

Description

Intervention group: In aromatherapy groups with citrus aurantium essential oil, 5 drops of citrus aurantium essential oil will be poured on a piece of cotton every night and for three consecutive nights and will be placed under the outer cover of the patient's pillow at a distance of about 20 cm from the nose. The cotton pad remains in place for 8 hours (10:00 PM to 6:00 AM).

Category

Other

3

Description

Control group: Participants in the control group will receive distilled water as a placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Seyedmohammad Mirhosseini

Street address

Imam Hossein Hospital, Emam St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

mirhoseinim@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Shahroud University of Medical Sciences, Tehran St., Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773947

Phone

+98 23 3239 5054

Email

emamian@shmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Seyedmohammad Mirhosseini

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, Tehran St.,
Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 3811

Email

smohammadmh@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Hossein Ebrahimi

Position

Professor of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, Tehran St.,
Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 3811

Email

ebrahimi@shmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Seyedmohammad Mirhosseini

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Shahroud University of Medical Sciences, Tehran St.,
Shahroud, Iran.

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone

+98 23 3239 3811

Email

smohammadmh@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some of the patient's demographic information can be
shared after unidentifying individuals. All of the patient's
sleep quality and symptoms of anxiety and depression
assessment information can be shared with unidentified
individuals.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Project partners

Under which criteria data/document could be used

People who do similar research.

From where data/document is obtainable

Requests to receive documents are sent to the project's
principal investigator (Seyedmohammad Mirhosseini) via
email (smohammadmh@gmail.com). Address: Tehran
St., Shahroud University of Medical Sciences, Shahroud,
Iran. Contact number: 00982332395054, postal code:
3614773955

What processes are involved for a request to access data/document

After receiving the request, the data will be provided to
the applicants by the project manager immediately via
email.

Comments