

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

Anxiety, depression and sleep quality

##### 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 Shahroud. 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

#### 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.

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**Province**

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**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

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

Shahroud University of Medical Sciences

**Full name of responsible person**

Syedmohammad 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**

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**Province**

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**Postal code**

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**Phone**

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**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**