Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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
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., Shahrood 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