Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

“The effect of inhalation aromatherapy with Citrus Aurantium essence on sleep quality and anxiety of patients with acute coronary syndrome”

Protocol summary

Study aim
The effect of inhalation aromatherapy with Citrus urantium essential oil on sleep quality and anxiety in patients with ACS

Design
Single blind RCT with one experimental group and one control group will be selected by block random sampling method on 84 eligible patients

Settings and conduct
The study will be Single blind RCT (evaluator is blind) with randomized division of patients into 2 groups (experimental and control) in the CCUs of Fatemeh Zahra Hospital in Sari.

Participants/Inclusion and exclusion criteria
Patients aged 18 years and older, hospitalized in the cardiac care at least 24 hours, acute coronary syndrome, stability of vital signs, non-addiction to drugs and alcohol, no mental disorders, no history of hospitalization due to psychological problems, lack of experience of stressful events in the last 6 months (except for events related to heart disease), Willingness to participate in the study, and Signing informed consent.

Intervention groups
The duration of aromatherapy is 2 consecutive nights and from 9 pm, after receiving the routine care, the patient is inhaled in the form of C.Aurantium essence. In the experimental subgroup 1&2, 1.5 cc of 30% C.Aurantium essential oil and in the control subgroups of 1&2, 1.5 cc of paraffin is poured on a cotton ball and patient is asked to take 3 breaths and then the cotton ball is attached to the patient's collar. The next morning at 7 o'clock, the cotton ball will be detached from the patient's collar. After 2 nights and in the morning of the third day, the quality of sleep and anxiety are measured again. allocating 2 control subgroups and 2 experimental subgroups for performing the intervention may lead us to achieving more accurate results.

Main outcome variables
sleep quality and anxiety in patients with acute coronary syndrome

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210523051370N3**
Registration date: **2021-08-21, 1400/05/30**
Registration timing: **prospective**

Last update: **2021-08-21, 1400/05/30**
Update count: **0**

Registration date
2021-08-21, 1400/05/30

Registrant information
Name
Seyed Afshin Shorofi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-20, 1400/06/29
Expected recruitment end date
2021-11-21, 1400/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
"The effect of inhalation aromatherapy with Citrus Aurantium essence on sleep quality and anxiety of patients with acute coronary syndrome"

Public title
Effect of aromatherapy with Citrus Aurantium essence on sleep quality and anxiety

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 years and older At least 24 hours have passed since admission to cardiac care unit Acute coronary syndrome diagnosed by treating physician Stability of vital signs No addiction to drugs and alcohol No mental disorders (such as Down syndrome and dementia) No history of hospitalization due to mental disorders Not experienced stressful events in the last 6 months (except for events related to their heart disease) Willingness to participate in the study

Exclusion criteria:
Pregnancy Breastfeeding History of allergies to essential oils and perfumes Acute respiratory diseases Shortness of breath and chronic cough

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The study design consists of an experimental group and a control group. Patients will be recruited using convenience sampling method and then will be randomly assigned to four groups by block randomization method. A quadruple block (A, B, C, D) will form letters A and B of the control group , the letters C and D of the patient to the experimental group. Using the letters A, B, C and D, 24 blocks of four are formed, which will be numbered from one to 24. Then, using Random Number Generator software, 21 numbers are selected from numbers 1 to 24. patients will be divided into two groups (one control group receiving aromatherapy with pure paraffin; one experimental group receiving aromatherapy with 30% Citrus Aurantium essence)

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will not be part of the research team and will be blind to participant allocation to study groups. The sharpness of the smell of aroma oil will be suppressed by adding a little oil to a face mask to be worn by the assessor during measurements.

Placebo
Used

Assignment
Parallel

Other design features
As patients will be recruited from several hospital wards, they will be divided into two groups, one control group (randomly divided into two subgroups) receiving aromatherapy with pure paraffin; one experimental group (randomly divided into two subgroups) receiving aromatherapy with 30% Citrus Aurantium essence) to reduce the impact of confounding variables. First, a comparison will be made between the two control subgroups as well as the two experimental subgroups. If there will be no difference between the two control subgroups and also between the two experimental subgroups, the final comparison between the experimental and control groups will be made. Otherwise, the CCU variable is considered as a moderating variable in the study and subsequently, a statistical analysis of the comparison between the two groups will be performed.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Biothics Committee of Mazandaran University of Medical Sciences

Street address
Sari, Moallem Square, Deputy of Research and Technology

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Mazandaran

Postal code
4815733971

Approval date
2021-05-11, 1400/02/21

Ethics committee reference number
IR.MAZUMS.REC.1400.098

Health conditions studied

1

Description of health condition studied
anxiety and sleep quality

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Anxiety
Timepoint
Basic (before intervention time: time zero), follow-up (after the end of two nights of intervention and in the morning of the third day: time two)
Method of measurement
Anxiety section of the Hospital Anxiety and Depression Scale (HADS-A)

2

Description
sleep quality
Timepoint
Basic (before intervention time: time zero), follow-up (after the end of two nights of intervention and in the morning of the third day: time two)
Method of measurement
Schneider-Halpren Sleepers Scale

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group : The duration of aromatherapy is two consecutive nights and from 9 pm, after receiving the routine care, in experimental groups one and two, 1.5 cc of 30% citrus aurantium essential oil (prepared by Noorhan Pharmaceutical Company, Shiraz, Iran, is poured on a cotton ball with a syringe and the patient is asked to take three deep breaths and then the cotton ball will be attached to the patient's collar. In the morning (7 o'clock in the morning), cotton ball will be removed from the collar of the patient's clothes.
Category
N/A

2

Description
Control group: The duration of aromatherapy is two consecutive nights and from 9 pm, after receiving the routine drugs of the ward, in control groups one and two, 1.5 cc of pure paraffin (prepared by Fadak Shimi Toos Company, Mashhad, Iran, is poured on a cotton ball with a syringe and the patient is asked to take three deep breaths and then the cotton ball will be attached to the patient's collar. In the morning (7 o'clock in the morning), cotton ball will be removed from the collar of the patient's clothes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh Zahra Educational and Medical Center
Full name of responsible person
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Imam Hossein Square, Army Boulevard, next to the Blood Transfusion Organization
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Seyed Afshin Shorofi

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Elderly health

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable