Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of inhalation aromatherapy with rose damascene on symptoms of pain, anxiety, and physiological parameters among patients with acute coronary syndrome: a Parallel Randomized Clinical Trial

Protocol summary

Study aim
Assessment of the effect of inhalation aromatherapy with rose damascene on symptoms of pain, anxiety, and physiological parameters among patients with acute coronary syndrome

Design
A phase III parallel randomized clinical trial, two groups; phase 3, uses a random blocking allocation that cannot be blinded and a sample size will be 70 people.

Settings and conduct
The setting of the study is Imam Hossein Hospital in Shahroud. Spielberger's standard anxiety questionnaires, visual analogue scale, and physiological indicators are completed by both groups before and 10 minutes after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of acute coronary syndrome by a specialist, Full consciousness (GCS=15) and the patient has been admitted to the emergency ward. Exclusion criteria: Acute psychological disorders, neuroleptic medication, opioid drug consumption before the intervention, allergy to plants and their scent, and olfactory disorders.

Intervention groups
In the aromatherapy group with rose essential oil, 5 drops of 40% rose essential oil will be attached to the patient's shirt and will be placed about 20 cm from the nose. The cotton piece remains in place for 20 minutes. In the control group, distilled water will be used as a placebo.

Main outcome variables
Anxiety, pain and physiological indicators

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180728040617N9**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date
2023-12-18, 1402/09/27

Registrant information
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Seyedmohammad Mirhosseini
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of inhalation aromatherapy with rose damascene on symptoms of pain, anxiety, and physiological

parameters among patients with acute coronary syndrome: a Parallel Randomized Clinical Trial

Public title
Effect of inhalation aromatherapy with rose damascene on symptoms of pain, anxiety, and physiological parameters among patients with acute coronary syndrome: a Parallel Randomized Clinical 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 emergency ward

Exclusion criteria:
Acute psychological disorders Neuroleptic medication Opioid drug consumption before the intervention Allergy to plants and their scent Olfactory disorders

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups with rose damascene and control by random block allocation using quadruple blocks created by SPSS software. According to the sample size of 70 people in the present study, 18 blocks of four will be considered. Each patient will be randomly assigned to the rose damascene aromatherapy group (A) and control group (B) 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 according to 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
2023-11-28, 1402/09/07

Ethics committee reference number
IR.SHMU.REC.1402.140

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 Spielberger Anxiety Questionnaire.

Timepoint
Before and 10 minutes after the end of the intervention

Method of measurement
Spielberger anxiety questionnaire

2

Description
Pain: Pain is the score that can be obtained from the visual analog scale.

Timepoint
Before and 10 minutes after the end of the intervention

Method of measurement
visual analog scale

3

Description
Physiological indicators: Physiological indicators mean blood pressure, pulse, breathing, temperature and oxygen saturation percentage of arterial blood.

Timepoint
Before and 10 minutes after the end of the intervention

Method of measurement
All indicators will be evaluated using Saadat monitoring device.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the aromatherapy group with rose essential oil, 5 drops of 40% rose essential oil will be attached to the patient's shirt and will be placed about 20 cm from the nose. The cotton piece remains in place for 20 minutes.
Category
Other

2

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
Masoumeh Ghorbanian
Street address
Imam Hossein Hospital, Emam St., Shahroud, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for scientific inquiries

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Full name of responsible person
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Assistant professor
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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 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 (Ali Abbasi) via email (abbasi_msn@yahoo.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