

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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

2023-12-22, 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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shahroud

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masomeghorbanian4@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Behzad Garmabi

Street address

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

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behzad.garmabi@gmail.com

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Ali Abbasi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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

Shahroud University of Medical Sciences

Full name of responsible person

Seyed Mohammad Mirhosseini

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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