

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of aromatherapy with rose essential oil on apparent anxiety in patients with myocardial infarction

Protocol summary

Study aim

Determination of apparent anxiety before and after inhalation of rose essential oil in myocardial infarction patients • Determination of hidden anxiety before and after inhalation of rose essential oil in myocardial infarction patients

Design

A randomised, blinded, controlled clinical trial with 80 patients

Settings and conduct

It is performed in patients with acute coronary syndrome in Heshmatieh Hospital. The data collection method is a questionnaire. In the intervention group, rose essential oil is used and in the control group, sesame oil is used for 3 days and patients' anxiety is recorded before and after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria were age of 40-80 years, literacy, no history of mental illness, conscious of time, place and person, having the first experience of acute chest pain, no addiction to smoking and drugs, no olfactory disorder, and the absence of asthma, respiratory problems, and a history of allergies to plant odors

Intervention groups

In addition to the routine treatment in the ward, the intervention group received three drops of REO (Barij Pharmaceutical Co., manufacturing license No. 4215 from the Ministry of Health). REO was poured on non-absorbable napkins with a dropper and pinned to the patients' collar. They were asked to breathe normally for 20-30 min, which was done 3 times a day with an interval of 30 min between inhalations for 3 days.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181208041891N1**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **retrospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Alemeh Dehnabi

Name of organization / entity

Tarbiat modares university of medical science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-29, 1399/11/10

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

2021-01-29, 1399/11/10

Actual recruitment end date

2021-06-05, 1400/03/15

Trial completion date

2021-06-20, 1400/03/30

Scientific title

The effect of aromatherapy with rose essential oil on apparent anxiety in patients with myocardial infarction

Public title

The effect of aromatherapy with rose essential oil on apparent anxiety in patients with myocardial infarction

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Having the first experience of acute chest pain Age of 30-70 years Having hemodynamic stability No history of mental illness, conscious of time, place and person Literacy Score 20 or higher on the overt and covert anxiety scale No olfactory disorder No addiction to smoking and drugs Absence of asthma, respiratory problems, and a history of allergies to plant odors

Exclusion criteria:

The use of benzodiazepines, sedatives, and opioids Sudden changes in hemodynamic status Dissatisfaction with patient cooperation during the study History of eczema and allergies to plants History of migraines and chronic headaches Active psychological disease as diagnosed by a physician Olfactory disorder

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling was purposeful and available. Eligible samples were randomly assigned to one of the two intervention (Inhalation aromatherapy) and control (Placebo inhalation) groups. The researcher, after the initial selection of the sample (according to the admission conditions) and the satisfaction of the patients, measured their anxiety using the Spielberger anxiety questionnaire. If the score was more than 20, the demographic characteristics form and the disease information form were completed. Depending on which group the patient was in, they received their own intervention. It should be noted that patients' rooms in the intervention group were different from that of the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants become blind using a placebo and unaware of the materials used. Due to the fact that the study was conducted by a sampler and recorded, the data were coded and sent by him to the outcome and data analyzer, these people are also considered blind.

Placebo

Used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Sabzevar University of Medical Sciences

Street address

Asad Abadi Ave, Sabzevar

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Razavi Khorasan

Postal code

9617913112

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.Medsab.rec.1395.124

Health conditions studied**1****Description of health condition studied**

Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes**1****Description**

Anxiety

Timepoint

Measure the level of anxiety before the intervention and then after the intervention daily for 3 days

Method of measurement

Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group received three drops of REO (Barij Pharmaceutical Co., manufacturing license No. 4215 from the Ministry of Health). REO was poured on non-absorbable napkins with a dropper and pinned to the patients' collar. They were asked to breathe normally for 20-30 min, which was done 3 times a day with an interval of 30 min between inhalations for 3 days

Category

Treatment - Other

2

Description

Control group: The control group received three drops of three drops of sesame oil (placebo) that was poured on non-absorbable napkins with a dropper and pinned to the patients' collar. They were asked to breathe normally for 20-30 min, which was done 3 times a day with an interval of 30 min between inhalations for 3 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatie hospital

Full name of responsible person

Mohammad Haddi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hussein Saqi

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammad Haddadi

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol is made available to the public through the writing and publication of the article.

When the data will become available and for how long

Access time after publication of the article

To whom data/document is available

Researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used

No specific point is considered

From where data/document is obtainable

Mohammad Haddadi m.Haddadi96@gmail.com

What processes are involved for a request to access data/document

Coordination with the Vice Chancellor for Research and Technology of Sabzevar University of Medical Sciences

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

Sabzevar University of Medical Sciences

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