Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effect of aromatherapy with Melissa Officinalis essene on Stress and Hemodynamic parameters of patients with acute coronary syndrome at Emergency unit

Protocol summary

Study aim
Determination of the effect of Melissa Officinalis essence on stress and hemodynamic parameters in patients with acute coronary syndrome

Design
The clinical trial has a control group, with parallel groups, three blind, randomized. The sample size is 72 patients.Computer randomization dedicated into two groups of intervention and control

Settings and conduct
The intervention is performed on two occasions in the emergency department. The aromatherapies interval is 90 minutes. Before the aromatherapy, stress level, threat perception, pain intensity, mean arterial pressure and heart rate are measured. They are re-measured 5 and 15 minutes after the end of aromatherapy. The threat perception questionnaire is used only at the beginning and end of the intervention.Blindness is performed in the researcher, the outcome assessor, the data analyst, and the participants

Participants/Inclusion and exclusion criteria
Stress score above 19 on the stress scale and Pain score of 3 and more from the visual analogue scale

Intervention groups
In the Melissa officinalis group, two drops of Melissa officinalis essence at 80% concentration and in the placebo group two drops of sunflower oil at 2% concentration with a dropper on an absorbent patch attached to the oxygen mask were given and the patient was asked to inhale it for 10 minutes. 5 minutes and again 15 minutes after the end of aromatherapy، the level of stress, pain , mean arterial blood pressure and heart rate will be measure. Completing the threat perception questionnaire is only at the beginning and end of the intervention. The aromatherapies interval is 90 minutes in emergency department. Aromatherapy will take place in the morning to evening shifts between 8:00 to 23:00.

Main outcome variables
Stress; Mean Atrial pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150919024080N14**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date
2019-12-07, 1398/09/16

Registrant information

Name
Mohammad Gholami

Name of organization / entity
Lorestan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with Melissa Officinalis essene on Stress and Hemodynamic parameters of patients with acute coronary syndrome at Emergency unit

Public title

The effect of Melissa on stress and hemodynamic parameters

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of acute coronary syndrome by a specialist based on evidence based electrocardiogram and clinical signs and troponin index No respiratory disease such as asthma and COPD and allergies or allergies to plants Entering the emergency department without cardiac arrest Vigilance and Awareness of place, time and person No history of head trauma and seizure No history of confirmed mental illness No opium and alcohol addiction No history of PTSD in during the last six months No history of using other complementary therapies for at least one month before intervention No disruption of sense of smell Mean arterial blood pressure more than 90 and heart rate more than 60 Patients with chest pain severity of 3 and more based on visual analogue scale (VAS) Age over 35 and under 65 years

Exclusion criteria:

Patients Candidate for primary PCI Patient's unwillingness to continue participation Unstable hemodynamic (20% change compared to time of start intervention) Incidence of arrhythmias and allergic and respiratory problems during intervention Transfer patients from the emergency department to the intensive care unit in less than 3 hours Patient connection to mechanical ventilation

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who meet the inclusion criteria will be assigned to the two study groups using stratified randomized block design (to match the two groups according to sex and severity of pain). In this way, the first stage of the patient's sex is considered and in different sex the severity of pain in the categories 3-6.9 and 7-10 is considered as the second floor and within the patient classes as 4 or 6 blocks with The use of the computer will be randomly assigned to the two study groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Melissa Officinalis essence and placebo will be poured into Barry's similar dark glass containers by Barij essence Company and the dishes will be coded by a person who has no role in the study and will be covered by a black bar. The code of the essential oil containers will remain with the research partner until the end of the analysis. The researcher, the statistical consultant, the interventionist, and study participants will be unaware of the contents of the dishes. The therapist will also use a nasal clip for 10 minutes during aromatherapy.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

Iran University of Medical Sciences, Lorestan, Khorram Abad, 5 Km.

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Postal code

381351698

Approval date

2019-09-07, 1398/06/16

Ethics committee reference number

IR.LUMS.REC.1398.144

Health conditions studied

1

Description of health condition studied

Acute coronary syndrom

ICD-10 code

I21.4

ICD-10 code description

Non-ST elevation (NSTEMI) myocardial infarction

2

Description of health condition studied
Stress
ICD-10 code
F43.0
ICD-10 code description
Acute stress reaction

3

Description of health condition studied
Aromatherapy
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Mean atrial pressure and Heart rate
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Stress score in DASS-21 questionnaire
Timepoint
Before intervention, 5 and 15 minutes after the end of aromatherapy on two occasions of aromatherapy
Method of measurement
DASS-21 Stress Questionnaire

2

Description
Mean Atrial Pressure
Timepoint
Before intervention, 5 and 15 minutes after the end of aromatherapy on two occasions of aromatherapy
Method of measurement
Cardiac Monitoring machine

3

Description
Heart rate
Timepoint
Before intervention, 5 and 15 minutes after the end of aromatherapy on two occasions of aromatherapy
Method of measurement
Cardiac Monitoring machine

4

Description
Threat perception score
Timepoint
Before and the end of intervention
Method of measurement
Threat Perception Questionnaire

Secondary outcomes

1

Description
قبل از مداخلهpain
Timepoint
Before the intervention, 5 and 15 minutes after the intervention in two aromatherapy treatments
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: Melissa officinalis essence 80%, one drop, two times and 90 minutes away،For 10 minutes at a time، Inhaler with oxygen mask، Adonis Pharmaceutical Company
Category
Other

2

Description
Control group: 2% sunflower oil, two drop, two times and 90 minutes away،For 10 minutes at a time، Inhaler with oxygen mask، Adonis Pharmaceutical Company
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Heart Hospital
Full name of responsible person
Atefe Veiskaramian
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Ebrahim Falahi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Doesnt have

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
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Position
Master student

Latest degree
Bachelor

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

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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available