Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Survey the effect of aromatherapy with peppermint essential oil on pain and Hemodynamic parameters in patients with acute coronary syndrome (ACS)

Protocol summary

Study aim

Determining the effect of aromatherapy with peppermint essential oil on pain and Hemodynamic parameters in patients with acute coronary syndrome (ACS)

Design

The current study is a randomized clinical trial with two groups (intervention and control). The patients who are eligible for the study are entered into the study using the available method and are randomly assigned to two groups of mint and placebo using the block method (blocks of four and with an allocation ratio of 1:1 using a random table of numbers). .

Settings and conduct

Subjects will be controlled and intervened into two equal groups using block randomization method. Aromatherapy will last 20 minutes. Complementary tool is performed after aromatherapy. This study will be conducted in the hospitals of Qom University of Medical Sciences

Participants/Inclusion and exclusion criteria

awareness of full consciousness, Age range 18-60 years Absence of valvular heart disease Serious illness Vision, hearing, and smell problems No damage and allergic problems No drug use Absence of kidney problems Not taking sedatives 4 hours before the intervention The absence of mental illness causes problems, stress, stress.

Intervention groups

In the control group, the patients will be treated with a non-absorbent eye pad with 0.2 ml of normal saline for 20 minutes, and for the intervention group, the same steps will be performed in another room, but instead of normal saline, the peppermint essential oil of Barij Essance Company will be used. 0.2 ml with a concentration of 100% is used on the pads, and in both groups the desired pads are attached to the clothes of the patients in the chest area by a pin.

Main outcome variables

pain Hemodynamic parameters anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221205056718N1**
Registration date: **2022-12-25, 1401/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-25, 1401/10/04**
Update count: **0**

Registration date

2022-12-25, 1401/10/04

Registrant information

Name

Hossein Sharafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3197 1087

Email address

hsharafi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Survey the effect of aromatherapy with peppermint essential oil on pain and Hemodynamic parameters in patients with acute coronary syndrome (ACS)

Public title
effect of aromatherapy with peppermint essential oil on pain and Hemodynamic parameters in patients with acute coronary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Full consciousness Age range 18-60 years Absence of valvular heart disease Severe disease conditions Any vision, hearing, or smell disorder Absence of respiratory and allergic problems No drug addiction Absence of liver and kidney problems Not taking sedatives 4 hours before the intervention No history of any confirmed mental illness such as depression, anxiety, stress
Exclusion criteria:
Sudden occurrence of any severe changes in vital signs and the presence of dangerous cardiac dysrhythmias in patients Unwillingness to continue participating in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who are eligible for the study are entered into the study using the available method and are randomly assigned to two intervention and control groups using the block method (blocks of four and with an allocation ratio of 1:1 using a random number table). . For example, the first four participants enrolled form the first block and the next four form the next block, and so randomization occurs within blocks, so with blocks of size four there are six possible patterns: AABB, ABAB, ABBA , BAAB, BABA, and BBAA, each block is randomized based on one of these six patterns, and the patterns are chosen randomly and generally independently from block to block.

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
Research Ethics Committee of Qom University of Medical Sciences
Street address
No. 83, Safashehr St., Shahid Lotfi Niaser- Shahid Lotfi Niaser Alley, Safashehr Street, Qom
City
Qom
Province
Ghoum
Postal code
93456-37169

Approval date
2022-11-21, 1401/08/30

Ethics committee reference number
IR.MUQ.REC.1401.174

Health conditions studied

1

Description of health condition studied
Diseases of the circulatory system

ICD-10 code
I20.1

ICD-10 code description
Angina pectoris with documented spasm

2

Description of health condition studied
complementary medicine

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Pain and hemodynamic symptoms

ICD-10 code

ICD-10 code description

4

Description of health condition studied
anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Pain related to aromatherapy
Timepoint
Before and immediately after intervention
Method of measurement
Visual Analogue Scale

2

Description
Anxiety related to aromatherapy
Timepoint
Before and immediately after intervention
Method of measurement
Depression Anxiety and Stress Scale 21 (DASS-21)

3

Description
Hemodynamic parameters
Timepoint
Before and immediately after intervention
Method of measurement
Digital heart monitoring system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Peppermint essential oil of Barij company is 0.2 ml of 100% essential oil that they inhale on the eye pads. Mint essential oil and placebo with similar appearance produced by Barij Essan Daru Company are placed in dark bottles with similar sizes and shapes. Aromatherapy for the control group and the intervention group in different places and periods of different uses related to acute stress, treatment, hemodynamic treatments and the intensity of chest pain before aromatherapy (time 1), 5 (time 2) and 15 (time) 3) minutes, 30 minutes after aromatherapy (time 4) after the first stage of aromatherapy, then after 30 minutes (1 hour of aromatherapy) the numbers of the study will be measured (time 5) and the second stage of aromatherapy The patient will be exposed to aromatherapy for 20 minutes. Changes in the study will be recorded at 5 (time 6) and 15 (time 7) and 30 minutes after the second phase of aromatherapy (time 8).
Category
Treatment - Drugs

2

Description
In the control group, the patients will be treated with a non-absorbent eye pad with 0.2 ml of normal saline for 20 minutes, and for the intervention group, the same steps will be performed in another room, but instead of normal saline, the peppermint essential oil of Barij Essance Company will be used. 0.2 ml with a concentration of 100% is used on the pads, and in both groups the desired pads are attached to the clothes of the patients in the chest area by a pin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qom Shahid Beheshti Hospital
Full name of responsible person
Majid Moghadam
Street address
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Email
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Web page address
https://bmc.muq.ac.ir/

2

Recruitment center
Name of recruitment center
Khyerin Salamat educational research and therapeutic complex
Full name of responsible person
Javad Hakim Elahi
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Postal code
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Web page address
https://nekuei.muq.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghoum University of Medical Sciences

Full name of responsible person
Mehdi Mesri

Street address
Qom - Shahid Lavasani St. (Saheli) - Qom University of Medical Sciences and Healthcare Services

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hsharafi@muq.ac.ir

Web page address
https://muq.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ghoum 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
Ghoum University of Medical Sciences

Full name of responsible person
Hossein Sharafi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Hossein Sharafi

Position
Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The second half of 1402

To whom data/document is available

There is no restriction on access to the results

Under which criteria data/document could be used

There are no restrictions after de-identifying people

From where data/document is obtainable

hossein sharafi tell:00989173596990
h_sharafi68@yahoo.com

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

There are no restrictions

Comments