

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of essential oil of Lavender aromatherapy on anxiety and vital signs in heart ischemia patients who hospitalized in CCU

Protocol summary

Summary

Cardiac patients particularly myocardial infarction (MI) in acute phase and first 48 hours after hospitalization, experience a lot of anxiety and in compare to patients who have less anxious, afflicted by ischemia, recurrent MI, tachycardia and ventricular fibrillation 5 times higher. Also, hospital wards due to noise, alien environment, disrupting in sleep and etc. are stressor. One of the non-drug methods for decreasing of anxiety that has attracted a lot of attention in recent years is aromatherapy. However, our scrutiny showing that there is no study about Lavender aromatherapy effect on decreasing anxiety in heart ischemic patients, as yet. So, the aim of this study is determine to effect of essential oil of Lavender aromatherapy on anxiety and vital signs in heart ischemia patients who hospitalized in Imam Reza and Imam Ali Hospitals of Kermanshah University of Medical Sciences in 2014.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030216797N1**

Registration date: **2014-05-03, 1393/02/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

Name

Hossein Ashtarian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1826 2052

Email address

hashtarian@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research project approved by Kermanshah University of Medical Sciences.

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of essential oil of Lavender aromatherapy on anxiety and vital signs in heart ischemia patients who hospitalized in CCU

Public title

Effect of essential oil of Lavender aromatherapy on anxiety and vital signs in heart ischemia patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: recorded the diagnosis of MI in accordance with physician diagnosis; Suffered from MI for the first time; No record of Allergic Rhinitis, Eczema or respiratory problems such as asthma and no olfactory dysfunction; No medical or uncontrolled infection disorder; Being aware of time, place and subject; Patient agreement for participating in study; No diagnosed mental illness; No drug addiction; the age between 25 to

65; Stable of vital signs; Having no pain at the time of interview and completing questioner; The ability to speak Persian; Gaining more than 20 of the Spielberg State-anxiety questionnaires score. Exclusion criteria: To be under CPR on arrival at the ED (emergency department) and CCU; Using sedative drugs without prescription during study; Patients suffering cardiac dysrhythmia, ventricular fibrillation, Ventricular tachycardia and cardiogenic shock; No cooperation during the study; Patient death during the study; Sensitivity to lavender aroma.

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Kermanshah University Of Medical Sciences

Street address

Kermanshah, Shahi Beheshti Blvd., Branch of researchs and industry of Kermanshah University Of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2014-01-08, 1392/10/18

Ethics committee reference number

49404

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

Ischaemic heart diseases

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

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

Anxiety

Timepoint

Before the intervention, 15 to 20 minutes after intervention in two consecutive days

Method of measurement

The questionnaire of Spielberger anxiety

Secondary outcomes

empty

Intervention groups**1****Description**

The first group (aromatherapy): The questionnaire of demographic information and Spielberger anxiety are completed before intervention. Then three drops of pure Lavender oil which were dripped on tissue, will be breathed by patients at 10 to 11 AM and 6 to 7 PM and each time for 20 minutes within two days (generally four sessions). Then the questionnaire of Spielberger anxiety will be completed again 20 minutes after intervention. In the second group (control): all procedures are same but Instead of lavender oil, we use distilled water.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza and Imam Ali Hospitals

Full name of responsible person

Hossein Ashtarian

Street address

Kermanshah, Kermanshah University of Medical Sciences, School of Nursing and Midwifery.

City

Kermanshah

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Kermanshah, Kermanshah University of Medical Sciences, Branch of researchs and industry.

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Hossein Ashtarian

Position

PhD, Chief of School of Nursing and Midwifery

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty