Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

Protocol summary

Study aim
To determine the effect of aromatherapy with essential oils of lavender and peppermint on the sleep quality of cardiac patients

Design
Clinical trials, with parallel groups, randomized

Settings and conduct
In this study, heart patients hospitalized in Imam Ali Hospital and eligible individuals were randomly divided into three groups (two intervention groups and one control group). For 7 nights at 22 o'clock, in group one, three drops of peppermint essential oil, in group two, three drops of lavender essential oil, and in group three (control group), three drops of distilled water, on a napkin, and held for 20 minutes by the gauze , Will be attached in the chest area.

Participants/Inclusion and exclusion criteria
inclusion criteria include Consent to participate in the study, positive reaction to smell, earn points equal to or more than five from the Pittsburgh sleep quality Index. Exclusion criteria include Unwillingness to continue to cooperate, and administering oxygen for patients.

Intervention groups
In group1,for seven nights at 22 o'clock,the three drops of Peppermint essential oil will be used.Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for20minutes. In group2:for seven nights at 22 o'clock, the three drops of lavender essential oil will be used. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes In control group: for seven nights at 22 o'clock, the three drops of distilled water and is connected to the patient's clothing at the chest and inhaled for20 minutes

Main outcome variables
sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201601244736N10**
Registration date: **2016-11-04, 1395/08/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-24, 1397/10/03**
Update count: **1**

Registration date
2016-11-04, 1395/08/14

Registrant information

Name
Alireza Khatony

Name of organization / entity
Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Kermanshah University of Medical Sciences

Expected recruitment start date
2016-10-22, 1395/08/01

Expected recruitment end date
2017-10-23, 1396/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

Public title
Comparative evaluation of the effect of aromatherapy with the essential oils of lavender and peppermint on cardiac patients' sleep quality

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Consent to participate in the stud positive reaction to smell he stability of vital signs (blood pressure, pulse, respiration and temperature) having aged 18 to 65 years earn points equal to or more than five from the Pittsburgh sleep quality Index Lack of sinusitis and Pneumonia no addiction to drugs and alcohol Being alert Passed 48 hours of admission not having mental disease and no history of hospitalization in psychiatric wards Do not take caffeine one hour before bedtime

Exclusion criteria:
Unwillingness to continue to cooperate Transition to other wards or death Receiving narcotic and oxygen during aromatherapy critically ill patient during the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Qualified samples were entered into the study by accessible method and randomly divided into intervention groups (peppermint and lavender) and control. Blocks were done as follows: To aromatic groups with peppermint essential oil and Lavender was assigned A and B codes respectively, and the control group received C code. The study blocks were ABC, ACB, BAC, BCA, CAB, CBA, BCC, CAB, CAB, and the ABC block was selected as the first block. Patients were assigned to peppermint, lavender, and control groups, respectively, and this method continued until the samples were completed.

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 Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City
kermanshah

Province
Kermanshah

Postal code
62663455667

Approval date
2016-09-28, 1395/07/07

Ethics committee reference number
kums.rec.1395.380

Health conditions studied

1

Description of health condition studied
Coronary Artery Disease

ICD-10 code
I25.1

ICD-10 code description
Coronary Artery Disease

2

Description of health condition studied
Myocardial infarction

ICD-10 code
I22

ICD-10 code description
Myocardial infarction

3

Description of health condition studied
Congestive heart failure

ICD-10 code
I50.0

ICD-10 code description
Congestive heart failure

Primary outcomes

1

Description
sleep quality

Timepoint
at the beginning of study and Eighth day
Method of measurement
Pittsburgh sleep quality questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In group I, for seven nights before going to sleep at 22 o'clock, the three drops of lavender essential oil will be used. Trade name of this essence is lavender essential oil and its scientific name is Lavandula stoechas which is produced by Tehran Zarband Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included are linalyl acetate and linalool. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.
Category
Other

2

Description
In group 2, for seven nights before going to sleep at 22 o'clock, the three drops of Peppermint essential oil will be used. Colpermin' is a pharmaceutical brand name for peppermint oil and Its scientific name is Mentha piperita which is produced by Tehran Zarband Company. This essential oil will be used in pure form with a concentration of 100 percent. Major chemical compounds included Menthol, Mentol and methyl acetate. Essential oils will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.
Category
Other

3

Description
In control group, for seven nights before going to sleep at 22 o'clock, the three drops of distilled water will be used which is produced by Tehran Samen Company. Distilled water will be dropped by the dropper on napkins and is connected to the patient's clothing at the chest and inhaled for 20 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital of Kermanshah
Full name of responsible person
Alireza Khatony
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Nursing Department, Kermanshah School of Nursing and Midwifery, Ashayer Street, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Behrooz Hamzeh
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Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran
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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
Vice chancellor for research, Kermanshah 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
Kermanshah School of Nursing and Midwifery

Full name of responsible person
alireza khatony

Position
PhD, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Not applicable

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
Yes - There is 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
The main consequence is the possibility of sharing information.

When the data will become available and for how long
Six months after the publication of the article

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
There is no right to extract the article from the documentation.

From where data/document is obtainable
Dr. Alireza Khatony

What processes are involved for a request to access data/document
Within a week of receiving the email, it will be answered.

Comments