Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of lavender essential oils and orange spring on pain, anxiety and restlessness of conscious patients admitted to intensive care units

Protocol summary

Study aim
Effect of lavender essential oils and orange spring on pain, anxiety, restlessness of conscious patients admitted to intensive care units

Design
Clinical trials with control group, with parallel groups, non-blind, randomized minimization

Settings and conduct
Patients admitted to the intensive care units of Afzalipoor and Bahonar hospitals in Kerman, who had criteria for entry, were randomly assigned into 3 groups (placebo, lavender and barnarjang).

Participants/Inclusion and exclusion criteria
Entry requirements: Normal sense of smell Failure to receive accommodation 3 hours before or during intervention Absence of severe anxiety disorder with doctor's diagnosis; Non-arrival conditions: The need for a sedative or sedative during the intervention

Intervention groups
Placebo group: In this group, in addition to the usual care of the area, a placebo (normal saline) is used. 5 normal saline drops are poured onto the gases and placed 10 cm from the nose of the patient and the patient is inhaled for 30 minutes. Lavender Essential Oil: In this group, in addition to the usual care of the lavender essential oil component, it is also used. 5 drops of lavender essence 2% on the gases and placed 10 cm away from the nose of the patient. The patient is required to inhale it for 30 minutes. Orange Spring Essential Oil: In this group, in addition to the usual care of the essential oil of the spring formula. 5 drops of 2% sparkling essential oil on the gases and placed at a distance of 10 cm from the nose of the patient. The patient is required to inhale it for 30 minutes.

Main outcome variables
Effect of lavender essential oil, orange spring and placebo on pain; Effect of lavender essential oil, orange spring and placebo on restlessness; Effect of lavender essential oil, orange spring and placebo on anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170116031972N9**
Registration date: **2019-11-14, 1398/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-14, 1398/08/23**
Update count: **0**

Registration date
2019-11-14, 1398/08/23

Registrant information

Name
Mahlagha Dehghan Anari

Name of organization / entity
Kerman University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of lavender essential oils and orange spring on pain, anxiety and restlessness of conscious patients admitted to intensive care units

Public title
Effect of lavender essential oils and orange spring on pain, anxiety and restlessness

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Able to read and write Normal sense of smell Stability of hemodynamic status Failure to receive accommodation 3 hours before or during intervention Absence of asthma and other chronic respiratory problems Do not miss the last 24 hours Absence of severe anxiety disorder with doctor's diagnosis Lack of eczema and allergies to plant and citrus substances

Exclusion criteria:
The need for a sedative or sedative during the intervention

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: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples were randomly assigned to intervention and control groups. The method of random allocation is such that the first sample is placed in one of three groups using the lottery, then according to the variables of sex and age (2 ±) and addiction in the three groups are matched. Assignment of samples will be continued using the lottery and according to the matched variables.

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 Kerman University of Medical Sciences

Street address
Campus of the University of Medical Sciences, Beginning of the Road of Seven Gardens

City
kerman

Province
Kerman

Postal code
76169-13555

Approval date
2019-07-06, 1398/04/15

Ethics committee reference number
IR.KMU.REC.1398.179

Health conditions studied

1

Description of health condition studied
Pain in vigilant patients in the intensive care unit

ICD-10 code
R52

ICD-10 code description
Pain, unspecified

2

Description of health condition studied
Restlessness in vigilant patients in the intensive care unit

ICD-10 code
R45.1

ICD-10 code description
Restlessness and agitation

3

Description of health condition studied
Anxiety in vigilant patients in intensive care units

ICD-10 code
F41.8

ICD-10 code description
Other specified anxiety disorders

Primary outcomes

1

Description
Effect of lavender essential oils and orange spring on pain

Timepoint
The pain rate was completed before and immediately before the study, 1 hour after the intervention (placebo, lavender essential oil and orange spring).

Method of measurement
VSA pain scale

2

Description
Effect of lavender essential oils and orange spring on

anxiety

Timepoint

The anxiety level was completed before the study immediately and 1 hour after the intervention (placebo, lavender and orange spring).

Method of measurement

Spielberger Anxiety Inventory

3

Description

Effect of lavender essential oils and orange spring on restlessness

Timepoint

The amount of restlessness was completed by the patient before and immediately and 1 hour after the intervention (placebo, lavender and orange spring).

Method of measurement

Richmond Rescue Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placebo (normal saline) is used for patients of this group in addition to the routine care (if the patient is suffering from pain, restlessness and anxiety, sedatives and haloperidol will be used according to the physician's order. Also, the doctor may request psychiatric counseling for the patient). First, the patient completes the pain, anxiety and restlessness questionnaire. Then, the gauze impregnated with 5 drops of normal saline is placed at a distance of 10 cm from the patient's nose (we will attach the gauze to the patient's collar). The patient is required to inhale it for 30 minutes. The pain, anxiety and restlessness questionnaire is recompleted by interviewing the patient immediately and one hour later.

Category

Placebo

2

Description

First intervention group: The lavender essential oil is used in this group, in addition to the routine care. First, the questionnaires are completed by interviewing patients. Then, the gauze impregnated with 5 drops of the lavender oil is placed at a distance of 10 cm from the patient's nose (2%) (Made by Barij Essence of Kashan) (We will attach the gauze to the patient's collar). The patient is required to inhale it for 30 minutes. The questionnaires are recompleted immediately and one hour later.

Category

Other

3

Description

Second intervention group: The orange blossom essential oil is used in this group, in addition to the routine care. First, the questionnaire is completed by interviewing the patient. Then, the gauze impregnated with 5 drops of the orange blossom essential oil (2%) (Made by Barij Essence of Kashan) is placed in a distance of 10 cm from the patient’s nose (we will attach the gauze to the patient's collar). The patient is required to inhale it for 30 minutes. The researcher will recomplete the questionnaires immediately and one hour later. It should be noted that sampling will be taken on the second day of the patient's admission to the intensive care unit. Also, sampling will be taken at 6-8 pm (due to reduced workload and patient's preparation for nighttime sleep). The questionnaires are completed by interviewing the patient. If the patient takes sedatives, the intervention will be done 3 hours later.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Zahra Karimzadeh

Street address

Afzalipour Hospital, next to Bahonar University, Imam Khomeini Highway

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2

Recruitment center

Name of recruitment center

Bahonar hospotal

Full name of responsible person

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Sponsors / Funding sources

1

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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
Kerman 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
Kerman University of Medical Sciences
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Zahra Karimzadeh
Position
Student
Latest degree
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Person responsible for updating data

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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
Results from this research are shared
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions and individuals in the industry
Under which criteria data/document could be used
Data and results are presented after the request is reviewed
From where data/document is obtainable
zahra karimzadeh Zahrakarimzadeh1391@gmail.com
What processes are involved for a request to access data/document
The request will be sent in writing to the Zahrakarimzadeh1391@gmail.com email address, after the review will be delivered to the requesting person.
Comments