

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5201

Email address

m_dehghan@kmu.ac.ir

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 ($2 \pm$) 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

City

Kerman

Province

Kerman

Postal code

76169-13911

Phone

+98 34 3132 8000

Email

Zahrakarimzadeh1391@gmail.com

2

Recruitment center

Name of recruitment center

Bahonar hospital

Full name of responsible person

Zahra Karimzadeh

Street address

Bahonar Hospital, Shahid Sepahbod Qarani Street

City

Kerman

Province

Kerman

Postal code

76137-47181

Phone

+98 34 3223 5011

Email

Zaharakarimzadeh1391@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

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

City

Kerman

Province

Kerman

Postal code

76169-13555

Phone

+98 34 3132 5600

Email

Zaharakarimzadeh1391@gmail.com

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

Full name of responsible person

Zahra Karimzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

Street address

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

City

Kerman

Province

Kerman

Postal code

76169-13555

Phone

+98 34 3132 5600

Email

Zaharakarimzadeh1391@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Zahra Karimzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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+98 34 3132 5600

Email

Zaharakarimzadeh1391@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Zahra Karimzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Postal code

76169-13555

Phone

+98 34 3132 5600

Email

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 Zaharakarimzadeh1391@gmail.com

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

The request will be sent in writing to the Zaharakarimzadeh1391@gmail.com email address, after the review will be delivered to the requesting person.

Comments