Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the inhalation effect of lavender essential oil on sedation levels in children hospitalized in the intensive care unit (ICU)

Protocol summary

Study aim
Determination of the inhalation effect of lavender essential oil on the level of sedation in children hospitalized in the intensive care unit (ICU)

Design
"A phase 1, double-blind, randomized, parallel-group, controlled clinical trial on 70 patients. The SPSS software block function was used for randomization.

Settings and conduct
In the placebo group, in addition to routine care, 5 drops of distilled water are inhaled for 30 minutes every eight hours. Similarly, the intervention group inhales 5 drops of lavender extract for 30 minutes every eight hours. Then, as per the routine of the intensive care unit, agitation scores will be assessed for all studied patients in each shift (every six hours) by the respected ICU nurse using the Richmond Agitation Sedation Scale (RASS). Subsequently, the amount of sedation medications used, as well as the mean Richmond sedation score over the 24 hours following the intervention, will be measured in both groups according to the guideline Shahid Bahonar hospital of kerman

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 12 to 18 years GCS greater than or equal to 8 extubated Exclusion Criteria: Intubation Patient death changes in hemodynamic

Intervention groups
Control group: In this group, in addition to routine ward care, a placebo (distilled water) is used. Five drops of distilled water are applied to gauze, which is then attached to the patient’s collar. The patient inhales from it for 30 minutes. Intervention group : In this group, in addition to routine ward care, lavender essential oil from Royaye Salamat Company is also used. Five drops of lavender extract from Royaye Salamat Company at a concentration of 2% are applied to gauze, which is then attached to the patient's collar at a distance of 10 centimeters. The patient inhales it for 30 minutes."

Main outcome variables
RASS score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101220005426N15**
Registration date: **2026-05-14, 1405/02/24**
Registration timing: **prospective**

Last update: **2026-05-14, 1405/02/24**
Update count: **0**

Registration date
2026-05-14, 1405/02/24

Registrant information

Name
Mehdi Ahmadinejad

Name of organization / entity
Anesthesiology department, Kerman University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 34 0223 5011

Email address
m.ahmadinejad@kmu.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-31, 1405/03/10

Expected recruitment end date
2026-12-30, 1405/10/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the inhalation effect of lavender essential oil on sedation levels in children hospitalized in the intensive care unit (ICU)

Public title

Investigating the Effect of Lavender on the Level of Sedation in Hospitalized Children in the ICU

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 12 to 18 years GCS greater than or equal to 8 Admitted to intensive care units (ICU) Patient extubated at the time of study entry Hemodynamic stability No known history of hypersensitivity to lavender or other aromatic herbal compounds No history of chronic respiratory diseases No clinical signs or diagnosis of active pulmonary aspiration No primary or secondary immunodeficiency disorders Having a normal sense of smell Written informed consent from the patient’s parent or legal guardian

Exclusion criteria:

Patient intubation Transfer of the patient to other units Patient death Sudden and significant changes in hemodynamic status Occurrence of any side effects

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the patients, a block randomization method with block sizes of 4, 6, and 8 (using SPSS software) will be used to assign individuals to the two groups. This method will also ensure concealment of allocation. In this approach, each individual will be assigned a unique code, which will be attached to the medication packages, thereby also facilitating the blinding process. Patients will be placed into either the intervention group (35 patients) or the placebo group (35 patients).

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double blinded study in which people will be divided into two control and intervention groups. Participants and data analyzers will not be not aware of the allocation of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Kerman University of Medical Sciences

Street address

Vice chancellor for research Kerman university of medical science, Jahad street

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2026-02-01, 1404/11/12

Ethics committee reference number

IR.KMU.AH.REC.1404.235

Health conditions studied

1

Description of health condition studied

Agitation rate

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Aromatherapy

Timepoint

At the beginning and end of the intervention

Method of measurement

Charted information

2

Description

RASS (Richmond Agitation-Sedation Scale) SCORE

Timepoint

At 0, 6, 12, 18, and 24 hours after the start of the intervention

Method of measurement
RASS table

Secondary outcomes

1

Description
BMI
Timepoint
At the beginning of the intervention
Method of measurement
File information

2

Description
Age
Timepoint
At the beginning of the intervention
Method of measurement
File information

3

Description
Gender
Timepoint
At the beginning of the intervention
Method of measurement
File information

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the routine care provided in the intensive care unit (for controlling anxiety and agitation, which includes the use of sedatives such as benzodiazepines—e.g., midazolam at an initial dose of 0.1 mg/kg and a maintenance dose of 0.05 mg/kg/h, or lorazepam at an initial dose of 0.05 mg/kg—and haloperidol at an initial dose of 0.04 mg/kg and a maintenance dose of 0.05 mg/kg/day if agitation occurs, based on physician's orders), lavender oil is also used to manage anxiety. The method involves soaking gauze with 5 drops of lavender extract (lavender essential oil from Royaye Salamat Company) at a 2% concentration, with a final linalool concentration of 0.5%. The gauze is placed 10 cm from the patient's collar every 8 hours, and the patient inhales the vapor for 30 minutes. This intervention will be repeated three times per patient and will last a total of 24 hours.
Category
Other

2

Description
Control group: In addition to routine intensive care unit (ICU) care (to manage anxiety and agitation, including the use of sedative benzodiazepines such as midazolam at an initial dose of 0.1 mg/kg and maintenance dose of 0.05 mg/kg/h, or lorazepam at an initial dose of 0.05 mg/kg, and haloperidol at an initial dose of 0.04 mg/kg and maintenance dose of 0.05 mg/kg/day if agitation occurs, as per physician's order), patients will receive a placebo (distilled water) to control anxiety. The method is as follows: 5 drops of distilled water are applied to gauze, which is then attached to the patient's collar at a distance of 10 cm, every eight hours. The patient inhales from it for 30 minutes. This intervention will be repeated three times per patient and will last a total of 24 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Bahonar hospital of Kerman
Full name of responsible person
Mehdi Ahmadinejad
Street address
Shahid Bahonar hospital, Qorani St, Valiasr crossroad
City
Kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
m.ahmadinejad@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Hamid Sharifi
Street address
Vice chancellor for research, Kerman University of Medical Science, Jahad street
City
Kerman
Province
Kerman
Postal code
7619813159
Phone
+98 34 3226 3719
Email
sharifihami@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
Mehdi Ahmadinejad

Position
Professor - Fellow of intensive care

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 0223 5011

Email
m.ahmadinejad@kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mehdi Ahmadinejad

Position
Professor - fellow intensive care

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 43 0223 5011

Email
m.ahmadinejad@kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Mehdi Ahmadinejad

Position
Professor - Fellow intensive care

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Shahid Bahonar Hospital, Qarani St, Valiasr Crossroads, Shariaati St, Kerman

City
Kerman

Province
Kerman

Postal code
7613747181

Phone
+98 34 0223 5011

Email
m.ahmadinejad@kmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available