Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Aromatherapy with Lavender Essential Oil Compared to Rosa Damascena on Reducing Delirium and Improving Clinical Outcomes in Multiple Trauma Patients in the Intensive Care Unit

Protocol summary

Study aim
To determine the effectiveness of inhalation aromatherapy with lavender essential oil compared to rose essential oil on reducing delirium and improving clinical outcomes in multiple trauma patients.

Design
Randomized clinical trial, placebo controlled, with parallel groups, double blind on 123 patients.

Settings and conduct
The study is conducted in the intensive care unit of Payambar e Azam educational and medical center in Bandar Abbas. Random allocation is concealed using opaque envelopes. Patients and outcome assessors are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Trauma patients aged 18 to 65 years; Injury Severity Score less than 15; Glasgow Coma Scale greater than 8; lack of sensitivity to herbal essential oils. Exclusion criteria: Baseline delirium; history of psychiatric disorders; olfactory disorders.

Intervention groups
The first group receives lavender essential oil, the second group receives rose essential oil, and the control group receives distilled water via inhalation with completely identical containers and conditions.

Main outcome variables
Incidence of delirium; severity of delirium; level of consciousness and agitation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240929063203N7**
Registration date: **2026-05-28, 1405/03/07**
Registration timing: **prospective**
Last update: **2026-05-28, 1405/03/07**
Update count: **0**

Registration date
2026-05-28, 1405/03/07

Registrant information

Name
Milad Mohammadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

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

Expected recruitment end date
2027-05-31, 1406/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effectiveness of Aromatherapy with Lavender Essential Oil Compared to Rosa Damascena on Reducing Delirium and Improving Clinical Outcomes in Multiple Trauma Patients in the Intensive Care Unit

Public title
Effectiveness of Aromatherapy with Lavender Essential Oil Compared to Rosa Damascena on Reducing Delirium

and Improving Clinical Outcomes in Multiple Trauma Patients in the Intensive Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged between 18 and 65 years Injury Severity Score (ISS) less than 15 Glasgow Coma Scale (GCS) score greater than 8 No known allergy or sensitivity to essential oils Providing informed consent to participate in the study

Exclusion criteria:

Presence of baseline delirium at admission History of psychiatric disorders Presence of olfactory disorders

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial, individual randomization is performed using block randomization with block sizes of 3, 6, and 9. Multiple trauma patients admitted to the intensive care unit of Payambar-e-Azam Educational and Medical Center who meet the inclusion criteria are randomly and equally assigned to three groups: two intervention groups (receiving lavender essential oil and rose essential oil) and a control group (receiving distilled water).

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial. In this investigation, patients (participants) and the nurses responsible for administering the intervention, outcome assessment, and clinical care will be completely blinded to the group allocation and the type of scent received. To maintain blinding, the intervention is carried out under the supervision of a blinded nurse, and patients in the control group will receive distilled water (as a placebo) with an identical appearance and inhalation method to the intervention groups (lavender and rose essential oils) so that no difference is perceived in the procedure. This design minimizes the risk of performance bias and detection bias.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Hormozgan University of Medical Sciences

Street address

Shahid Chamran Boulevard, University of Medical Sciences and Health Services, Bandar Abbas.

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Postal code

7916613885

Approval date

2026-01-27, 1404/11/07

Ethics committee reference number

IR.HUMS.REC.1404.346

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2

Description of health condition studied

Multiple trauma

ICD-10 code

M12.59

ICD-10 code description

Traumatic arthropathy, multiple sites

Primary outcomes

1

Description

Incidence of delirium in admitted patients.

Timepoint

Daily from the beginning of the study for 5 days (or until discharge from the intensive care unit if discharged earlier).

Method of measurement

Clinical assessment/0-7 points

2

Description

Mean score of delirium severity.

Timepoint

Daily from the start of the intervention for 5 days (or until discharge from the intensive care unit).

Method of measurement

Clinical assessment/0-8 points

3

Description

Patient’s level of consciousness, sedation, and agitation.

Timepoint

Daily from the beginning of the intervention for 5 days (or until discharge from the intensive care unit).

Method of measurement

Richmond Agitation-Sedation Scale.

Secondary outcomes

1

Description

Length of stay in the intensive care unit

Timepoint

From the time of admission until discharge from the intensive care unit

Method of measurement

Recording the number of hospitalization days based on the clinical records

2

Description

Length of hospital stay

Timepoint

From admission to final discharge from the hospital

Method of measurement

Recording the total number of hospitalization days by reviewing the medical records

3

Description

Duration of mechanical ventilation

Timepoint

From intubation to successful extubation (weaning from the ventilator)

Method of measurement

Calculating the days and hours on mechanical ventilation recorded in nursing reports

4

Description

Consumption of sedative and antipsychotic medications

Timepoint

Daily during the intervention period (up to 5 days) or until discharge from the intensive care unit

Method of measurement

Recording the total dose and type of received medications by reviewing physician orders and pharmacological records

5

Description

Pain intensity

Timepoint

Daily assessment for 5 days or until discharge from the intensive care unit

Method of measurement

Using standard pain assessment tools (e.g., behavioral pain scales for unconscious patients or Visual Analogue Scale)

6

Description

Mortality rate

Timepoint

During the hospitalization period

Method of measurement

Recording the patient’s survival or death status in the medical records

Intervention groups

1

Description

Intervention group: After randomization, patients in the first intervention group receive aromatherapy with pure lavender essential oil in addition to standard ICU care. The essential oil is certified for purity and quality and has a minimum purity of 98%. A sterile 4×44×4 gauze pad is impregnated with 5 drops of lavender essential oil and placed approximately 10 cm from the patient’s nose (attached to the patient’s collar). Patients are instructed to inhale the aroma for 30 minutes. The intervention is performed once daily between 8–9 AM for five consecutive days or until ICU discharge, whichever occurs first.

Category

Treatment - Other

2

Description

Intervention group: Patients in the second intervention group receive aromatherapy with pure Rosa damascena (rose) essential oil in addition to standard care. The administration protocol is identical to the lavender group. A sterile 4×44×4 gauze pad impregnated with 5 drops of rose essential oil is placed approximately 10 cm from the patient’s nose, and the patient inhales the aroma for 30 minutes. The intervention is administered once daily between 8–9 AM for five consecutive days or until ICU discharge.

Category

Treatment - Other

3

Description

Control group: Patients in the control group receive standard ICU care only and no aromatherapy

intervention. To maintain blinding, a similar container with distilled water is placed near the patient’s pillow to mimic the intervention conditions.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
The Great Prophet's (PBUH) educational, therapeutic and research center

Full name of responsible person
Pejman Shahrokhi

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number
4040438

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

Title of funding source
Bandare-abbas 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
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Full name of responsible person
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Anesthesiology

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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