Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of aromatherapy with lavender essential oil on pain intensity and sleep quality in patients with sickle cell disease

Protocol summary

Study aim
Determining the effect of lavender aromatherapy on pain intensity and sleep quality in patients with sickle cell disease

Design
This randomized, single-blind, parallel-group clinical trial includes 56 patients, with randomization conducted via permuted blocks of four using www.sealedenvelope.com

Settings and conduct
This two-group randomized clinical trial at Baghaei 2 Hospital, Ahvaz, will randomly assign participants to an intervention (lavender essential oil) or control (placebo) group. Both assessor and researcher will be blinded, and pain intensity and sleep quality will be measured using standardized self-report instruments pre- and post-intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Definitive diagnosis of sickle cell disease Age between 18 and 65 years Willingness to participate in the study and provision of written informed consent Ability to read and write in Persian Intact olfactory function A score of 5 or higher on the Pittsburgh Sleep Quality Index A score of 3 or higher on the Numeric Rating Scale for pain intensity Exclusion Criteria: Presence of severe psychiatric disorders Pregnancy Use of complementary medicine therapies Current or past (within the previous 12 months) diagnosis of stimulant, cannabinoid, or hallucinogen use disorder, alcohol use disorder, or high-risk alcohol consumption Diagnosis of opioid use disorder Presence of acute illnesses or unstable medical conditions Presence of chronic respiratory diseases

Intervention groups
Participants in the intervention group applied three drops of 100% pure lavender essential oil onto a 2 × 2 cm cotton pad each night at 10:00 PM for two weeks, attaching it to their clothing collar at 20 cm and removing it at 8:00 AM. The control group received aromatherapy in the same manner using a placebo (sweet almond oil).

Main outcome variables
Pain intensity and sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260120068622N1**
Registration date: **2026-02-27, 1404/12/08**
Registration timing: **prospective**

Last update: **2026-02-27, 1404/12/08**
Update count: **0**

Registration date
2026-02-27, 1404/12/08

Registrant information

Name
Zahra Abdollahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-09, 1404/12/18

Expected recruitment end date
2026-05-08, 1405/02/18

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy with lavender essential oil on pain intensity and sleep quality in patients with sickle cell disease

Public title

The effect of lavender on pain intensity and sleep quality in patients with sickle cell disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of sickle cell disease based on valid medical documentation and standard laboratory tests (such as hemoglobin electrophoresis) Age between 18 and 65 years Willingness to participate in the study and to provide informed consent Ability to read and write in Persian (for completing the questionnaires) Intact olfactory function based on self-report and a simple olfactory test A score of 5 or higher on the Pittsburgh Sleep Quality Index (PSQI) A score of 3 or higher on the Numeric Rating Scale (NRS) for pain intensity

Exclusion criteria:

Presence of severe psychiatric disorders (based on medical records). Pregnancy. Use of complementary medicine approaches (such as yoga and massage). Presence of stimulant substance use disorders (e.g., amphetamines), cannabinoid use disorders, hallucinogen use, or alcohol use or high-risk alcohol consumption within the past 12 months (based on medical records or self-report). Presence of opioid use disorder (according to clinical criteria or evidence of misuse as determined by the treating physician). Presence of acute illnesses or unstable medical conditions that would preclude safe participation in the study (based on medical records or self-report). Presence of confirmed chronic respiratory diseases such as asthma and chronic obstructive pulmonary disease.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be conducted using a convenience sampling method. To allocate participants to the two groups, namely the “intervention” and “control” groups, a four-part block randomization method will be used. In this method, all eligible participants will first enter the allocation process. Then, by forming blocks consisting of four participants, group allocation will be performed randomly while maintaining an equal allocation ratio. In each four-part block, two participants will be assigned to the intervention group and two participants to the control group. The website www.sealedenvelope.com will be used to generate random blocks for assigning participants to the groups. Considering that this study includes two groups, the four-part blocks may be arranged as follows: • C C M M • C M C M • M C M C • M M C C • C M M C • M C C M In these combinations, C denotes the control group and M denotes the intervention group. Subsequently, these six blocks will be numbered and randomly selected from among them (for example, using a random number table or software). Then, these blocks will be placed sequentially to form the randomization sequence, and allocation to the control and intervention groups will be performed using block randomization without blinding.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because of the nature of aromatherapy, blinding of participants is not feasible; therefore, in the present study, blinding will be applied at the level of the researcher and the outcome assessor. In this regard, both the researcher and the assessor will be unaware of the type of aroma received by the participants.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Esfand Shomali St., Golestan Alley, Ahvaz, Khuzestan

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2025-12-28, 1404/10/07

Ethics committee reference number

IR.AJUMS.REC.1404.524

Health conditions studied

1

Description of health condition studied
sickle cell disease
ICD-10 code
D57
ICD-10 code description
Sickle-cell disorders

Primary outcomes

1

Description
Pain intensity score measured by the Brief Pain Inventory.
Timepoint
Measurement of pain intensity at the beginning of the study (before the intervention) and 14 days after the start of lavender essential oil administration (after the end of the intervention).
Method of measurement
Brief Pain Inventory

2

Description
Pain intensity score on the Numeric Rating Scale.
Timepoint
Measurement of pain intensity at the beginning of the study (before the intervention) and on days 7 and 14 after the start of lavender essential oil administration.
Method of measurement
Numeric Rating Scale for pain intensity.

3

Description
Sleep quality score on the Pittsburgh Sleep Quality Index.
Timepoint
Measurement of sleep quality at the beginning of the study (before the intervention) and 14 days after the start of lavender essential oil administration (after the end of the intervention).
Method of measurement
Pittsburgh Sleep Quality Index.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will be instructed to, for two weeks, place three drops of 100% pure lavender essential oil, prepared by Barij Essence Kashan Pharmaceutical Company, onto a 2 × 2 cm cotton pad each night at 22:00 before bedtime. The cotton pad will then be attached to the collar of their clothing at a distance of 20 cm from the neck and removed in the morning at 08:00 upon waking. The placement and attachment procedure of the cotton pad to the collar will be demonstrated to the participants practically by the researcher.
Category
Other

2

Description
Control group: Participants in the control group will be instructed to, for two weeks, place three drops of 100% pure sweet almond oil, prepared by Barij Essence Kashan Pharmaceutical Company, onto a 2 × 2 cm cotton pad each night at 22:00 before bedtime, attach it to the collar of their clothing at a distance of 20 cm from the neck, and remove it in the morning at 08:00 upon waking. The placement and attachment procedure of the cotton pad to the collar will be demonstrated to the participants practically by the researcher.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Baghaei 2 Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Vice Presidency for Research and Technology
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Zahra Abdollahi
Position
Master of Science Student in Medical-Surgical Nursing
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Dataset title: Data dictionary for the study on the effect of aromatherapy with lavender essential oil on pain intensity and sleep quality in patients with sickle cell disease Sharing plan details: The data dictionary includes: • Definitions of all demographic variables of participants • Definitions of variables related to primary and secondary outcomes (pain intensity, sleep quality) • Data coding methods and measurement units • Permissible values and range for each variable • Description of data standardization and coding procedures This data dictionary enables researchers to accurately analyze and interpret the study data while ensuring that no identifiable participant information is included.

When the data will become available and for how long

The study-related data and documents (including de-identified individual participant data, the data dictionary, statistical analysis plan, final protocol, informed consent form, and clinical study reports) will be available to qualified researchers from the time of publication of the primary study results.The data and documents will remain accessible for up to five years after the publication of the primary results, which is a standard period allowing for secondary analyses and further scientific use.

To whom data/document is available

The study data and documents will be available only to qualified researchers. Qualified researchers are defined as individuals with a verified academic or scientific background in the relevant field and who can provide a clearly defined research proposal with specific scientific objectives. Eligible recipients may be affiliated with universities, research centers, or other recognized scientific institutions. Industry-based researchers may also request access, provided that the intended use is for scientific purposes and ethical considerations are fully addressed.

Under which criteria data/document could be used

The provided data and documents may only be used for scientific and research purposes directly related to the study topic. Researchers requesting access must submit a detailed research proposal clearly outlining the objectives, methods, and types of analyses planned on the data. Permitted analyses include: • Examination of primary and secondary study outcomes • Secondary statistical analyses with valid scientific objectives • Meta-analyses or systematic reviews based on the provided data Use of the data for commercial or promotional purposes is not permitted. All researchers must adhere to research ethics, confidentiality, and participant anonymization. Accompanying documents may be used solely to support scientific analyses and interpretation of the data and must not be reproduced or redistributed without permission.

From where data/document is obtainable

The study data and documents will be available through direct communication with the corresponding author. Interested researchers must submit a formal request via official institutional email to the corresponding author. Upon review and approval by the research team, the requested data and documents will be provided in encrypted format through secure data transfer methods. The data will not be deposited in a public repository, and access will be granted exclusively through formal communication with the research team.

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

Researchers seeking access to the study data and documents must follow these steps: 1. Submit a formal request: The researcher must send a formal request via official institutional email to the corresponding author. The request should include a detailed research proposal specifying objectives, methods, and planned analyses. 2. Scientific and ethical review: The research team will review the request for scientific validity and ethical compliance. This step typically takes 2 to 4 weeks, depending on the complexity of the request and the number of requests received. 3. Approval and preparation of data and documents: Upon approval, the requested data and documents will be prepared in a secure, de-identified format. This preparation usually takes 1 to 2 weeks. 4. Delivery to the requester: The data and documents will be delivered to the approved researcher through secure data transfer methods.

Comments