Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Lavender Aromatherapy on the Behavioral Reactions of Preterm neonate in the neonatal intensive care unit.

Protocol summary

Study aim
effect of lavender aromatherapy on behavioral reactions of preterm neonates

Design
The clinical trial has a control group with single-blind, parallel groups, randomized, phase 3, on 86 infants. RANDOM ALLOCATION SOFTWARE will be used for the randomization sequence.

Settings and conduct
This study will be conducted in the neonatal intensive care unit of Ghaem Hospital in Mashhad. In the intervention group, behavioral reactions will be recorded before the intervention begins. The newborn will be subjected to lavender aromatherapy for one hour. Immediately after the aromatherapy is completed and half an hour later, behavioral reactions will be scored according to the ABSS scale.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Neonatal age 28-34 weeks gestation Under non-invasive ventilation Having stable vital signs Apgar score at birth at 5 minutes above 6 No invasive procedure performed on the newborn 2 hours ago Absence of all types of neonatal anomalies Informed parental consent. Exclusion criteria: Gestational age greater than 34 weeks Addicted mother,intubated neonate,neonate has nasal cannula, Using narcotics and sedatives

Intervention groups
In the intervention group, infants will be exposed to lavender aromatherapy for one hour. Infants will be observed for 30 seconds over two consecutive days, once before the aromatherapy is applied, twice after the aromatherapy begins, once immediately after the aromatherapy ends, and a second time half an hour after the aromatherapy ends, and their behaviors will be recorded using the Anderson behavioral scale.The study will be conducted over two consecutive days from 3:00 PM to 5:00 PM, .In the control group, No scent will be used for this group, and the behavioral response will be examined.

Main outcome variables
Behavior.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250712066456N1**
Registration date: **2025-09-04, 1404/06/13**
Registration timing: **prospective**

Last update: **2025-09-04, 1404/06/13**
Update count: **0**

Registration date
2025-09-04, 1404/06/13

Registrant information

Name
maedeh robabi

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
2025-09-23, 1404/07/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Lavender Aromatherapy on the Behavioral Reactions of Preterm neonate in the neonatal intensive care unit.

Public title

The Effect of Lavender Aromatherapy on the Behavioral Reactions of Preterm neonate in the neonatal intensive care unit.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of newborns 28-34 weeks of pregnancy Apgar score at birth at 5 minutes above 6 Lack of various neonatal anomalies The baby has not had an invasive procedure performed on him/her within the last 2 hours. Having stable vital signs

Exclusion criteria:

Edict's mother Gestational age greater than 34 weeks Using narcotics and sedatives for the baby Intubate neonate Nasal cannula neonate.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the sequence of random allocation of individuals to the studied groups uses the method of replaced blocks and software Random Allocation Software. Due to the sample size of 43 cases per group, the first of the six possible blocks of four blocks of four "AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5) and BAAB (6)" was selected by accident and then the individuals were assigned to Group B and A. For example, if the first block, ABBA, is selected, the first and fourth person will be assigned to Group A and the second and third to Group B. This will continue until the sample size is completed. The characteristic of this method is that the two study groups will have equal number.

Blinding (investigator's opinion)

Single blinded

Blinding description

It is inserted into the incubator to blind the aroma by a person. Group A is the intervention group and group B control. Due to the random sequence selected, the fragrance is inserted for one hour. Babies are kept in the incubator, which is a completely closed environment and there is no fragrance release. After an hour of evaluation, the evaluation of the neonates under study and scores the behavioral reaction of infants. The statistical analyst will also perform the analysis and interference without knowing the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of mashhad University Medical science

Street address

Ferdowsi University kharazmi complex

City

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Province

Razavi Khorasan

Postal code

9177949025

Approval date

2025-07-15, 1404/04/24

Ethics committee reference number

IR.MUMS.NURSE.REC.1404.050

Health conditions studied

1

Description of health condition studied

Behavioral reaction of premature neonate

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Behavioral Reactions of Preterm neonate

Timepoint

Before the intervention, immediately after the intervention, half an hour after the intervention

Method of measurement

Anderson Behavioral Scale system.(ABSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: : The scent of lavender is placed ten centimeters away from the baby's head for one hour. The behavioral response of the infants will be observed for 30 seconds once before placing the lavender scent in the incubator, and twice after the aromatherapy is completed, once immediately after the aromatherapy is completed, and the second time half an hour after the aromatherapy is completed, and will be determined using the Anderson tool and recorded in a table. The study will be conducted from 3:00 PM to 5:00 PM, after feeding and routine nursing care, to minimize confounding factors. During the study, the infants' breathing rate and heart rate will be monitored to maintain patient safety.We dissolve one drop of 100% water-soluble lavender essential oil from the company Gaya Kala with 4 cc of warm distilled water and use it. The concentration of the solution obtained will be one percent.Linalool and linalyl acetate are the two main ingredients effective in calming.Dilution will be performed using standard droppers in the laboratory.

Category

Behavior

2

Description

Control group: In routine conditions and according to the intervention group's schedule, the behavioral response of premature infants will be recorded according to the Anderson instrument. This study will be conducted after feeding and routine nursing care, from 3:00 PM to 5:00 PM in order to reduce confounding factors. During the study, the respiratory rate and heart rate of the infants will be monitored to maintain patient safety. .

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

ghaem hospital

Full name of responsible person

maedeh robabi

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Mashhad, Ahmadabad Street, Shariati Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodi

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Mashhad, University Street, Central Building, Mashhad University of Medical Sciences, Vice Chancellor 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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

MAEDEH ROBABI

Position

MASTER STUDENT

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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
Not applicable

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

Title and more details about the data/document
The behavioral response of premature infants, which is the main outcome of this study, will be presented.

When the data will become available and for how long
After the publication of the article

To whom data/document is available
Academic and industrial researchers

Under which criteria data/document could be used
Academic and industrial researchers

From where data/document is obtainable
Maedeh Rababi, Master's student, Mashhad School of Nursing, Pediatric and Neonatal Department

What processes are involved for a request to access data/document
Send your request via email, it will be responded to as soon as possible.

Comments