

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of aromatherapy with Rosa damascenes on the sleep state of premature neonates admitted to the neonatal intensive care unit of Ali ebne Abitaleb hospital in Zahedan ,2020

Protocol summary

Study aim

Determining the effect of aromatherapy with Rosa damascenes on the sleep state of premature neonates admitted to the neonatal intensive care unit of Ali ebne Abitaleb hospital in Zahedan ,2020

Design

The clinical trial study is a randomized double-blind.64 samples will be divided into intervention and control groups by alternative block method.The size of all the blocks is equal.

Settings and conduct

Among the neonates admitted to the NICU of Zahedan's Ali Ibn Abi Talib Hospital, which have the criteria for entering the study, sampling is performed by sampling block method in two groups of intervention (The smell of Rosa Damascenes) and control (Distilled water) will be assigned.The newborn is placed embryocally in the nest inside the double-walled incubator.The newborn sleeps for 20 minutes before, 70 minutes during,20 minutes after placing the pad soaked in Rosa Damascenes, which is 30 cm away from the newborn 's head, at intervals of both.According to the Als's tool,the type of sleep status is determined and recorded in the instrument table. In order to perform the course in this research,sampling and interventions will be performed with the help of the researcher. All interventions will be recorded by the video camera.

Participants/Inclusion and exclusion criteria

Age between 30 and 37 fetal weeks No history of drug abuse in the mother Lack of severe respiratory distress having consent form parents Not having a chest tube and a umbilical catheter Does not use of sedative drugs for the neonate Not having icterus,congenital abnormalities,seizures

Intervention groups

Intervention group(The smell of Rosa Damascenes)
control group(Distilled water)

Main outcome variables

Premature infant's sleep:Observing the newborn's behavior using the Als's Sleep and AwakeningTools,which includes 6 deep sleep conditions A.B,light sleep A.B,drowsiness A.B,by the researcher

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036599N4**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **prospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

freshte ghaljaei

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 33442481

Email address

ghaljaei-f@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-05, 1399/07/14

Expected recruitment end date

2020-12-18, 1399/09/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of aromatherapy with Rosa damascenes on the sleep state of premature neonates admitted to the neonatal intensive care unit of Ali ebne Abitaleb hospital in Zahedan ,2020

Public title
The effect of aromatherapy with Rosa damascenes on the sleep state of premature neonates

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 30 and 37 fetal weeks Sustainable physiological symptoms Lack of severe respiratory distress No history of drug abuse in the mother Completion of the infant consent form for participation in research by parents
Exclusion criteria:
Having a chest tube and a umbilical catheter Use of narcotic, sedative and anesthetic drugs for the neonate Having diseases: icterus, congenital neurological abnormalities, meningitis, seizures, encephalopathy and interstitial hemorrhage

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The permuted block stratified randomization method will be used. The stratified randomization method allows the elimination of possible heterogeneities between the two groups in terms of age and sex. Also, the block randomization method provides the possibility of creating a balance in the number of samples assigned to each of the study groups. The randomization method is that the participating infants are classified at the beginning of the arrival in terms of age (30-33 and 33-37 weeks) and sex (girl-boy). In the next step, the infants will be assigned individually to group A or B according to the quadruple blocks. Random sequence of quadruple

blocks will be selected as ABAB / ABBA / BAAB / BABA / AABB / BBAA from the random number table. The classification and blocking process will continue until the study sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research,sampling and intervention will be done with the help of the researcher. All interventions will be recorded by the video camera . First, the researcher will be placed on the newborn's bed to evaluate and complete the form while examining the infant's sleep status and then the researcher will review the film's information to confirm the accuracy and the final score will be given. Researchers are unaware of the newborn's sleeping position on the newborn's bed , as well as the researcher's help when watching the recorded video of the intervention and control group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr. Hassabi Square, Janat Blvd, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2019-11-18, 1398/08/27

Ethics committee reference number

IR.ZAUMS.REC.1398.383

Health conditions studied

1

Description of health condition studied

Premature neonate's sleep

ICD-10 code

P07.0

ICD-10 code description

Extremely low birth weight newborn

Primary outcomes

1

Description

Sleep status of preterm neonate

Timepoint

During 20 minutes before the intervention, 70 minutes during intervention and 20 minutes after the intervention

Method of measurement

Observation the behavior of neonate with use of sleep and waking scale of Als, by researcher and helpre

Secondary outcomes

1

Description

Physiological signs of the neonate

Timepoint

Before, during and after the intervention

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention group: The baby is placed embryonically in the nest inside a double-walled incubator. The type of sleeping position of the baby within 20 minutes, according to the Ales tool, is determined every 2 minutes before, during and after placing the pad soaked in Zahra's organic rose at a distance of 30 cm from the baby's head and is recorded in the table.

Category

Treatment - Drugs

2

Description

Control group: The baby is placed embryonically in the nest inside a double-walled incubator. The type of sleeping position of the baby within 20 minutes, according to the Ales tool, is determined every 2 minutes before, during and after placing the pad soaked in "Distilled water" at a distance of 30 cm from the baby's head and is recorded in the table.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali al- Ibn Abi Talib Hospital in Zahedan

Full name of responsible person

Fereshteh Ghaljaei

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Dr. Hassabi Square, Janat Blvd, Zahedan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

NoorMohamad Bakhshani

Street address

Dr. Hasabie Square, Persian Gulf Blvd, Pardis Office Complex, Zahedan University of Medical Sciences and Health Services

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Web page address

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Grant name

Grant code / Reference number

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

No

Title of funding source

Zahedan University of Medical Sciences and Health Services

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

<http://zaums.ac.ir>

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Ghaljaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Mashahir square, Faculty of Nursing and Midwifery,
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Other areas of specialty/work

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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

The main outcomes of the participants are public.

When the data will become available and for how long

The main outcomes of the participants are public.

To whom data/document is available

The researchers in academic and scientific institutions.

Under which criteria data/document could be used

The statistical result.

From where data/document is obtainable

Faculty of Nursing and Midwifery, Zahedan Telephone:
05433442481 Postcode: 9816913396 Address: Mashahir
Square, Nursing and Midwifery Faculty, Zahedan

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

Contact the Nursing Faculty Library section.

Comments

does not have.