

# 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

#### Street address

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

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9816913396

#### Phone

+98 54 3329 5572

#### Fax

+98 54 3329 5572

#### Email

Ghaljaei-f@zaums.ir

#### Web page address

<http://zaums.ac.ir>

## 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

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

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##### Email

bakhshani@zaums.ac.ir

##### Web page address

<http://zaums.ac.ir>

#### 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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**City**

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**Province**

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**Postal code**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fereshteh Ghaljaei

**Position**

Associate Professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fereshteh Ghaljaei

**Position**

associate professor

**Latest degree**

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**Other areas of specialty/work**

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**Web page address**

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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.