

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of fetal position on sleep-wake cycle in premature infants

Protocol summary

Study aim

Effect of fetal position on sleep-wake cycle in premature infants

Design

To determine the sample size, the pilot study will be with ten infants. The sample includes neonates hospitalized in the Hospital who had the initial criteria of the study and were chosen using a convenience sampling technique. The randomly-assignment of the infants to the two groups of fetal position and supine position will follow this procedure: On two cards with the same size and shape the letters A and B will be written and a colleague—who does not know about the card information with regard to the position— will be asked to choose a card which represents the position. If the chosen card is A, the infant will be placed under the fetal position and if it is B, the infant will be placed under the supine position.

Settings and conduct

This study will be conducted in the Ali ibn Abi Talib Hospital in Zahedan using a crossover and randomized design. The chosen infants will be randomly assigned into the control and test groups and will be examined. Before applying the intervention, the infants will be fed and all the medical procedures, if needed, will be carried out. After three hours, the infant's position will be changed by a well-trained nurse.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The pregnancy week between 33-36; The second day after the birth; The birth weight between 1200-2000 gr. Exclusion criteria: Infant death

Intervention groups

The infants will be randomly assigned into two groups. Before applying the intervention, the infants will be assessed and will be fed. In the supine position group (Control), they will be put loosely and with their hands free sleeping in the incubator. Infants' sleep-wake cycle under the investigation will be observed for 20 minutes using the method of Als. If required, the infants will be fed after three hours and the required medical

interventions will be applied. The infants will be moved gently to a fetal position by a well-trained nurse. In this group, a nest will be placed around the infant and their hands will have flexibility in a way that the arms and legs of the curved baby are placed in the middle of the line and the hands are placed in front of their face so that the infants can put his hands to his mouth. The sleep-wake cycle will be assessed for twenty minutes using the method of Als.

Main outcome variables

The Development of sleep-wake cycle in Premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036599N3**

Registration date: **2018-02-22, 1396/12/03**

Registration timing: **retrospective**

Last update: **2018-02-22, 1396/12/03**

Update count: **0**

Registration date

2018-02-22, 1396/12/03

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

Ex: Personnel costs 4200000 Rials B: Total costs of testing and specialized services C: Collecting equipment and supplies 2020000 Rials D: Total Travel Costs 2800000 E: Total fees 3060000 Rials Total cost (Rials): 2604000

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fetal position on sleep-wake cycle in premature infants

Public title

Effect of fetal Position on sleep-wake cycles in premature infant

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The pregnancy week between 33-36 The second day after the birth The birth weight between 1200-2000 gr. Absence of congenital anomalies in the baby The lack of the need to use mechanical ventilation Contraindications for change Position Lack of growth defects within the uterus No consumption of aminophylline or caffeine in the neonate Lack of substance abuse in the mother

Exclusion criteria:

Infant death The presence of neurological disorders such as seizure and intraventricular hemorrhage of the grades 3 and 4 Congenital infections in the baby The presence of severe conditions requiring the use of therapies such as sedation The unwillingness of the mother to continue with in the study The need for surgery

Age

From **2 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **10**

After conducting a pilot study to be determined

Randomization (investigator's opinion)

Randomized

Randomization description

The randomly-assignment of the infants to the two groups of fetal position and supine position will follow this procedure: On two cards with the same size and shape the letters A and B will be written and a

colleague—who does not know about information on the card with regard to the position— will be asked to choose a card which represents the position. If the chosen card is A, the infant will be placed under the fetal position and if it is B, the infant will be placed under the supine position.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

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

Khalij Fars Blvd., Dr. Hesabi Square Campus, Research & Technology Dept. of Zahedan University of Medical Sciences,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

153.IR.ZAUMS.REC.1396

Health conditions studied**1****Description of health condition studied**

Premature infants

ICD-10 code

p07.1 - p0

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified Other low birth weight

Primary outcomes**1****Description**

sleep-wake cycle in 5 hours

Timepoint

for 20 minutes on each position

Method of measurement

Sleep Diagram scale Doctor Elas

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: In the intervention group (fetal position), the infants will be moved to a fetal position by a well-trained nurse. In this group, a nest will be placed around the infant and their hands will have flexibility in a way that the arms and legs of the curved baby are placed in the middle of the line and the hands are placed in front of their face so that the infant can put his hands to his mouth. The sleep-wake cycle will be assessed for twenty minutes using the method of Als.

Category

N/A

2

Description

The control group: After three hours since the intervention, the infants will be moved to a supine position by a well-trained nurse. In this group, they will be put loosely and with their hands free sleeping in the incubator. Infants' sleep-wake cycle under the investigation will be observed for 20 minutes using the method of Als.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib Hospital

Full name of responsible person

Freshte ghaljaei

Street address

Dr Hasabi Square, Ali ibn Abi Talib Hospital

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ameri13539879@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The Zahedan University of Medical Sciences

Full name of responsible person

Nor Mohammad Bakhshani

Street address

Dr Hesabi Square, Assistant Professor of 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

The Zahedan 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

2

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nor Mohammad Bakhshani

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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

Zahedan 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

Ph.D.

Other areas of specialty/work

Pediatrics

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Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

zahra ameri

Position

Senior Child Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Pediatrics

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Latest degree

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Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

freshteh ghaljaei

Position

Assistant Professor

Latest degree

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