

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of positioning with an octopus doll on the behavioral responses of premature infants under non-invasive ventilation

Protocol summary

Study aim

Determining the effect of positioning with an octopus doll on the behavioral responses of preterm infants under non-invasive ventilation

Design

Clinical trial with control group, crossover, double-blind, randomized using envelope method and with a sample size of 25. The study is a cross-sectional design and 25 infants under study are also in their control group.

Settings and conduct

Twenty-five preterm infants between the ages of 28 and 34 weeks will be admitted to the NICU of Ommolbanin Hospital under non-invasive ventilation who meet the inclusion criteria. Behavioral reactions are recorded during the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: parental consent, infant 28 to 34 weeks, maximum 24 hours after the start of non-invasive ventilation, No invasive procedure was performed on the infant 2 hours before admission to the study, no contraindications to change position, no drug use in the mother during pregnancy and after Delivery, not using drugs that affect the sleep-wake cycle of the baby, not prescribing sedatives, having a 5 minute Apgar score higher than 6, not having surgery on the baby after birth. Exclusion criteria: Congenital and chromosomal abnormalities, asphyxia, intracerebral hemorrhage more than first grade, sepsis, heart disease, metabolic, anemia. SGA and IUGR.

Intervention groups

To perform the intervention, in the supine position, the octopus doll will be placed in the baby's arms and the doll's feet will be in contact with the baby's body and hands. The babies of the first group will be placed in the fetal position for the first 2 hours. In the second 2 hours, they will be placed in the fetal position with the touch of an octopus doll, and in the babies of the second group, the opposite will be done. The neonates under study are also used as their control group.

Main outcome variables

Behavioral responses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201007048967N1**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

Registrant information

Name

Kimia Razi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

Email address

razik961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-23, 1399/08/02

Expected recruitment end date

2021-04-22, 1400/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of positioning with an octopus doll on the behavioral responses of premature infants under non-invasive ventilation

Public title

The effect of positioning with an octopus doll on the behavioral responses of premature infants under non-invasive ventilation

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Guardian parent's consent for the infant to participate in the study infant age in the range of 28 to 34 weeks (based on LMP or sonography of the first trimester of pregnancy) under non-invasive ventilation maximum 24 hours after the start of non-invasive ventilation No invasive procedure was performed on the infant 2 hours before admission to the study no contraindications to change position no drug use in the mother during pregnancy and postpartum no use of drugs that affect the sleep and wake cycle of the baby such as theophylline, phenobarbital lack Prescribing sedatives such as midazolam and fentanyl Having an Apgar score of 5 minutes above 6 no surgery on the infant after birth

Exclusion criteria:

Congenital and chromosomal abnormalities asphyxia intracerebral hemorrhage more than first grade sepsis heart disease metabolic disease anemia SGA and IUGR

Age

From **7 months** old to **8 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to two groups using the envelope method. This is how the envelopes will be prepared and printed by one of the members of the research team and random numbers with the help of Randomaize.com site and will be placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the infant's parents, and if they wish, they sign the informed consent form and take an envelope, and then open it, and based on the contents of the envelope, the infant enters the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the subjects under study who are premature infants are not aware of the study and also the analyst will be unaware of the intervention and control groups.

Placebo

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research School of Nursing and Midwifery - Mashhad University of Medical Science

Street address

School of Nursing and Midwifery., Ibn Sina St, Ph.D. Intersection., Daneshgah St, Mashhad, Khorasan Razavi

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9137913199

Approval date

2020-08-03, 1399/05/13

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.038

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

behavioral responses of premature infants

ICD-10 code

P07.3

ICD-10 code description

preterm infants

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

behavioral response of premature infants (sleep, wakefulness and restlessness)

Timepoint

Behavioral reactions of premature infants will be observed 2 minutes before the intervention, 2 minutes during and 2 minutes after the intervention and in each turn will be observed for 30 seconds and will be recorded in the relevant form.

Method of measurement

In this study, the infant's behavioral response is assessed using the Anderson Behavioral Reaction Scoring System (ABSS), which measures the infant's behavior with sleep, wakefulness, and restlessness. This scoring system determines a baby's behavioral status based on observation of respiratory order, open or closed eyes, trunk and limb activity, and crying intensity. The scoring system consists of 12 levels and behavioral states are classified into three categories: sleep, wakefulness, and restlessness. The scores are 1-5 related to sleep, 6-8 points related to wakefulness and rest, and 9-12 points related to restlessness. Based on this ABSS tool, 2 minutes before, 2 minutes during and 2 minutes after the intervention and at each turn for 30 seconds, the reactions of the baby's behaviors will be observed and recorded in the relevant form. In the Anderson Behavior Scoring System, the infant is observed for 30 seconds and the number corresponding to the highest behavioral state observed is recorded with one exception: Conscious Inactivity, which is a desirable but relatively rare state when it occurs. It is possible even if another state with the highest number occurs in the same 30 seconds, because conscious inactivity is a desirable state in infants

Secondary outcomes

1

Description

Timepoint

Method of measurement

2

Description

Timepoint

Method of measurement

Intervention groups

1

Description

Intervention group: The infants of the first group will be placed in the fetal position for the first 2 hours and then in the second 2 hours they will be placed in the fetal position with the touch of an octopus doll. In this study, the octopus doll is placed in the baby's arms and the doll's feet are placed in contact with the baby's body and hands. And the interventions will be repeated for 3 consecutive days in a fixed evening shift.

Category

N/A

2

Description

Control group: In the infants of the second group, they will be in contact with the doll in the first 2 hours and the doll will be removed from the baby in the second 2

hours. For the wash out phase, the babies will be in a supine position for 2 hours.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin hospital

Full name of responsible person

Hamidreza Behnam Vashani

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Corner of Ayatollah Behjat 16, Zarrineh Crossroads, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Rabab Latifnejad Rudsari

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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

Kimia Razi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

All data can potentially be shared after unidentified individuals.

When the data will become available and for how long

The start of the access period is 2 months after the results are published.

To whom data/document is available

The data will be made available to researchers working in academic and scientific institutions and to people in the relevant industry and to the relevant ministry.

Under which criteria data/document could be used

If this study has a positive effect, the effect of touching

an octopus doll on the behavioral response of a premature infant under non-invasive ventilation can be used as a useful and acceptable solution to reduce stress and help calm the infant in the neonatal intensive care unit. As a result, increased relaxation is the most important element in the development of the premature nervous system.

From where data/document is obtainable

Kimia Razi: razik961@mums.ac.ir Phone: 09156516202
Hamidreza Behnam Vashani: behnamhr@mums.ac.ir
Phone: 09151109514

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

The applicant must communicate via the contact number and e-mail address provided.

Comments