Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison the Effect of the White noise and Sound reduction on Behavioral Responses of Premature Infants under Non-invasive Ventilation

Protocol summary

Study aim
Comparing the effect of white noise and noise reduction on behavioral reactions of premature infants under non-invasive ventilation

Design
A randomized double-blind crossover clinical trial on 32 premature infants will be randomized to group 32 neonates into groups A and B. Block size 4 will be used.

Settings and conduct
Research in Hakim Hospital of Neyshabur Neonatal Intensive Care Unit Using Double-blind Randomized Clinical Trial

Participants/Inclusion and exclusion criteria
Inclusion criteria "Premature infants 28 weeks to 36 weeks gestation under noninvasive ventilation. Exclusion of "term newborns" and neonates without invasive ventilation and neonates undergoing invasive ventilation.

Intervention groups
32 preterm infants in the range of 28-36 weeks will be included in the study under noninvasive ventilation in NICU of Hakim Hospital of Neyshabur who meet the inclusion criteria.

Main outcome variables
The effect of noise reduction and white noise on behavioral responses of premature infants under non-invasive ventilation is similar.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230709058729N1**
Registration date: **2023-07-13, 1402/04/22**
Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**
Update count: **0**

Registration date
2023-07-13, 1402/04/22

Registrant information

Name
Mahdieh Mohseni kakhki

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
2023-07-22, 1402/04/31

Expected recruitment end date
2023-11-21, 1402/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the Effect of the White noise and Sound reduction on Behavioral Responses of Premature Infants under Non-invasive Ventilation

Public title
" the Effect of the White noise on Behavioral Responses of Premature Infants" "the Effect Sound reduction on Behavioral Responses of Premature Infants "

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parental Consent for Infant Participation in Research The baby's age ranges from 28 to 36 weeks and 6 days (based on LMP or ultrasound) Be under non-invasive ventilation and have not been at most 24 hours since the onset of non-invasive ventilation No invasive action was taken on the infant 2 hours before entering the study. Normality of OAE test No Counter-Indication to Change Positions Lack of drug use in the mother during pregnancy and after childbirth Not taking medications that affect the baby's sleep-wake cycle, such as theophylline, phenobarbital Lack of sedatives such as midazolam and fentanyl Absence of congenital abnormalities such as meningocele and meningomyelocele, meningitis, seizures, encephalopathy, congenital anomalies, asphyxia, intracranial hemorrhage greater than first-degree, sepsis, heart disease, metabolic and anemia. The baby is not SGA or IUGR. Having an Apgar score of 5 minutes above 6 Surgery on the baby after birth.

Exclusion criteria:

Poor baby (loss of consciousness, spo2 drop and change of vital signs from normal range) Dissatisfaction of the parent of the guardian to the continuation of the infant's participation in the research Infant death during the study Infant Transfer Need for invasive procedures during intervention Prescription of sedative drugs during intervention Developing neurological disorders such as seizures, grade 3 and 4 ventricular bleeding, sepsis Need for surgery Severe medical conditions that require the use of treatments such as sedatives, muscle relaxants, and analgesic medications Performing LP in baby Inappropriate medical condition, such as an unstable clinical condition Need for surgery

Age

From **28 days** old to **36 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked. { This method is used to prevent significant imbalances in the number of participants assigned to each group. Block randomization ensures that there is no significant imbalance between groups during randomization and at certain points the number of participants in each group is equal.Then write the list of blocks and assign numbers to them. (AABB(1)- ABAB(2)- ABBA(3)-BBAA(4)- BABA(5)- BAAB(6)) .Then select random numbers between 1 to 6(for example 1 4 5 ...) and finally specify the treatment allocation list based on the previous random numbers (... AABB-BBAA-BABA-) .}

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are premature infants and consent is obtained from their parents, so infants are unaware and are blind. The analyst is a statistical consultant who analyzes the data collected during the study.

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 of Medical Sciences

Street address

Faculty of Nursing and Midwifery located at the intersection of Doctora (Ibn Sina St. and University)

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Province

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Approval date

2023-07-07, 1402/04/16

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.051

Health conditions studied

1

Description of health condition studied

behavioral responses of premature infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Behavioral response score of premature infant

Timepoint

Behavioral response score of preterm infant 2 minutes before, during and 2 minutes after intervention

Method of measurement

Infant Behavioral Reactions Registration Form Using Anderson Behavioral Response Scoring System (ABSS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study is a randomized clinical trial with cross-sectional design. The cross design used in this study is standard cross design 2x2 BA/AB). 32 preterm infants in the range of 28-36 weeks will be included in the study under non-invasive ventilation in NICU of Hakim Hospital of Neyshabur who meet the inclusion criteria.Behavioral responses of preterm infants will be assessed and recorded 2 minutes before intervention, 2 minutes during and 2 minutes after intervention using Anderson's Behavioral Response Scoring System (ABSS). It should be noted that the time to observe and evaluate the behavior of the infant is 30 seconds at each stage.

Category
Behavior

2

Description
Control group: In standard crossover design (BA/AB 2 x2), the infants in the intervention group are self-control

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Neonatal Intensive Care Unit of Neyshabur Hospital

Full name of responsible person
Monir Ramezani Farmad

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Sponsors / Funding sources

1

Sponsor

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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
Mahdieh Mohseni kakhki

Position
Master of science in nursing

Latest degree
Bachelor

Other areas of specialty/work
Master of science in nursing

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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