Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

Protocol summary

Summary

The current research is a clinical trial study, in which samples were selected using nonprobability purposive convenience sampling method, divided into 3 groups and enrolled into the study based on inclusion criteria. In this study, 75 infants with 48 hours old and gestational age between 28 to 34 weeks hospitalized in neonatal intensive care unit at Imam Reza and Omolbanin Hospitals in Mashhad, Iran, in addition to routine care, received recorded sound of mother's heartbeats twice a day for eight consecutive days. The infants in control group received routine care and silent headphones for 40 minutes. The infants in intervention group received recorded sound of mother's heartbeats for 20 minutes in addition to routine cares. The placebo group listened to the recorded sound of another person's heartbeats for 20 minutes. Each intervention for all three groups included a forty-minute period. The first ten minutes involved baseline measurements prior to playing the sound. In the second and third ten minutes, recorded sound of mother's heartbeats was played for the intervention and placebo groups. Finally, the sound was stopped and the related measurements were performed after playing the recorded sound in the fourth ten minutes. Data collected in each intervention included oxygen saturation percentage, heartbeat per minute, respiratory rate per five minutes and duration of deep sleep after playing the sound. An expert did infant hearing screening after discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080629210N1**
Registration date: **2016-12-19, 1395/09/29**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-12-19, 1395/09/29

Registrant information

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Zahra Yazdani
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School of Nursing and Midwifery, Mashhad
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Recruitment status

Recruitment complete

Funding source

Mashhad University Of Medical Sciences

Expected recruitment start date

2016-05-17, 1395/02/28

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

Public title

The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: the infant must have spontaneous breathing and needs no mechanical ventilation; parents should be willing and consent to participate in the study; birth weight over 1000 g , no congenital abnormalities; lack of hearing problems in newborns; 28 to 34 weeks of gestational age; lack of clear infection; no maternal addiction. Exclusion criteria: need for assisted mechanical ventilation during the intervention; unwillingness of parents to continue to participate in the project; Grade 3 and 4 intraventricular hemorrhage; history of alcohol and coffee consumption; successive apnea; incidence of seizures in newborns; hearing problems; intrauterine growth restriction (IUGR); anemia with hemoglobin≤ 10 g/dL(hemoglobin less or equal to 10 grams per deciliter)

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

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 Science

Street address

Daneshgah Street

City

mashhad

Postal code

Approval date

2016-05-09, 1395/02/20

Ethics committee reference number

IR.MUMS.REC.1395.72

Health conditions studied

1

Description of health condition studied

Premature infant

ICD-10 code

P07

ICD-10 code description

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

Primary outcomes

1

Description

The duration of deep sleep

Timepoint

After intervention

Method of measurement

Ales doctor tools

2

Description

Respiratory rate

Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Observation

3

Description

Heart rate

Timepoint

Q 1 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Monitor

4

Description

Oxygen saturation

Timepoint

Q 1 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement

Monitor

Secondary outcomes

empty

Intervention groups

1

Description

Group I: Control group: Infants receive no intervention in this group and they will be monitored in terms of dependent variables for 40 minutes. The headphone will be placed on the infants' ears for 40 minutes, but no sound will be played.

Category

Other

2

Description

Group II: Placebo: The recorded sound of another person's heartbeats will be played at 50 dB intensity for infants through headphones for 20 minutes.

Category

Other

3

Description

Group III: intervention: The recorded sound of mother's heartbeats will be played at 50 dB intensity for infants through headphones for 20 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Imam Reza Hospital

Full name of responsible person

Zahra Yazdani

Street address

City

Mashhad

2

Recruitment center

Name of recruitment center

Mashhad Omolbanin Hospital

Full name of responsible person

Zahra Yazdani

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research, Mashhad University Of Medical Sciences

Full name of responsible person

Tayebeh Reyhani

Street address

Faculty of Nursing and Midwifery

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor For Research, Mashhad University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Zahra Yazdani

Position

Master Student of Neonatal Intensive Care

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University Of Medical Sciences

Full name of responsible person

Dr Ahmad Shah Farhat

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Neonatologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty