Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of binaural music and mothers lullaby on some physiological indicators and pain caused by endotracheal suction in term newborns hospitalized in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Protocol summary

Study aim
The effect of binaural music and maternal lullaby on pain reduction and improvement of physiological indices in neonates admitted to NICUs of hospitals affiliated with Shiraz University of Medical Sciences

Design
The clinical trial has a controlled, triple-blind, randomized design on 60 neonates, and Random Allocation software will be used for group assignment.

Settings and conduct
This study will be conducted in the NICUs of Namazi, Zeynabiyeh, and Hafez hospitals in Shiraz. All neonates will receive routine NICU care, and the intervention group will receive binaural music and maternal lullaby. To reduce bias, outcome assessors will be blinded to group allocation (triple-blind).

Participants/Inclusion and exclusion criteria
Neonates with endotracheal tube requiring suction Gestational age 38–42 weeks Postnatal age 1–28 days Verified auditory ability and response to auditory stimuli No sedative medications 4 hours prior to suction No severe congenital anomalies, intracranial hemorrhage > grade 2, or neurological disorders Parental consent to participate Exclusion criteria: Parental withdrawal of consent Unstable physiological condition or systemic complications Invasive procedures within 30 minutes before intervention

Intervention groups
Both the intervention and control groups will receive routine and first-line NICU care. The intervention group, in addition to routine care, will be exposed to music therapy including binaural music and maternal lullaby. The intervention will be applied 5 minutes before suctioning, during suctioning, and 5 minutes after suctioning.

Main outcome variables
Neonatal pain intensity, heart rate, and oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250820066925N1**
Registration date: **2025-09-20, 1404/06/29**
Registration timing: **prospective**

Last update: **2025-09-20, 1404/06/29**
Update count: **0**

Registration date
2025-09-20, 1404/06/29

Registrant information

Name
Saghi Eslamzadeh

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
2025-09-23, 1404/07/01

Expected recruitment end date
2025-10-23, 1404/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of binaural music and mothers lullaby on some physiological indicators and pain caused by endotracheal suction in term newborns hospitalized in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Public title

Comparison of the effect of binaural music and mothers lullaby on some physiological indicators and pain caused by endotracheal suction in term newborns hospitalized in neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Instability of the infant's physiological status or any other systemic disorder Having an endotracheal tube Need for endotracheal suctioning Gestational age between 38 and 42 weeks Postnatal age 1 to 28 days Do not use sedatives 4 hours before suctioning. Confirmation of hearing ability in infants and response to sound stimuli (examination will be performed by a doctor) Absence of congenital anomalies, intracranial hemorrhage greater than grade 2, or neurological problems No invasive procedure for the infant at least 30 minutes before the intervention No substance abuse or use of sedatives by the mother

Exclusion criteria:

Parents' unwillingness to continue cooperating during the research Instability of the infant's physiological status or any other systemic disorder

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible neonates, after obtaining written informed consent from their parents, will be randomly assigned into three groups: binaural music (A), maternal lullaby (B), and control (C). Randomization will be performed using stratified permuted block randomization with Random Allocation software. A pre-prepared randomization list will be generated by the principal investigator. Sampling will continue until the required number is completed, with 60 neonates distributed equally (20 in each group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be conducted using a triple-blind design. The intervention provider, the outcome assessor (research assistant responsible for recording physiological indicators and scoring the videos), and the statistical analyst will all remain unaware of group allocation (binaural music, maternal lullaby, or neutral control sound). Audio files will be coded as X, Y, and Z, and only the code custodian will have access to the actual intervention type. To minimize the risk of unblinding, the control group will receive a neutral, uniform sound at the same decibel intensity as the other groups, ensuring that the intervention conditions appear identical across groups. In addition, upon completion of the study and in line with ethical principles, relaxing music educational files will be provided virtually to the parents of infants in the control group.

Placebo

Used

Assignment

Parallel

Other design features

All three groups will receive routine neonatal pain management. Intervention group A will additionally receive binaural beat music with controlled decibel levels from 10 minutes before suction until 10 minutes after. Intervention group B will receive a recorded maternal lullaby under the same conditions. The control group will wear silent headphones for the same duration to ensure similarity across groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences, Shiraz University of Medical Sciences Research Committee, Fac

Street address

Building No. 2, Hazrat Fatima College of Nursing and Midwifery, Namazi Hospital, Namazi Square, Shiraz, Iran

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Postal code

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Approval date

2025-08-02, 1404/05/11

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1404.059

Health conditions studied

1

Description of health condition studied
Term newborns admitted to intensive care units
ICD-10 code
P05.14
ICD-10 code description
Newborn small for gestational age, 1000-1249 grams

Primary outcomes

1

Description
Reduction of neonatal pain intensity during and after suction
Timepoint
10 minutes before suction, during suction (catheter insertion), and 10 minutes after suction
Method of measurement
Neonatal Infant Pain Scale (NIPS) based on video recordings assessed by a trained assistant

Secondary outcomes

1

Description
Changes in physiological indices (heart rate, oxygen saturation)
Timepoint
minutes before suction, during suction (catheter insertion), and 10 minutes after suction
Method of measurement
Recording of heart rate and oxygen saturation using a calibrated monitor and pulse oximeter

Intervention groups

1

Description
Intervention Group 1: Binaural Music, Infants in this group will receive binaural music from 10 minutes before the tracheal suctioning procedure until 10 minutes after it. The music will be played through standard headphones at a controlled sound intensity of 35–45 dB. The selected binaural beat music has a frequency of 10 Hz in the alpha wave range (produced by Miracle Tones and streamed via Spotify). The sound level will be measured and adjusted using the Sound Meter Pro application to ensure it remains within a safe range.
Category
Treatment - Other

2

Description
Intervention group 2: Mother’s Recorded Lullaby, Infants in this group will listen to their mother’s recorded lullaby from 10 minutes before the tracheal suctioning procedure until 10 minutes after it. The lullaby is recorded in a quiet room, preferably the one sung by the mother during pregnancy or intended for the infant. If a suitable room is not available in the ward, the mother may record the lullaby at home following the researcher’s guidance. The recorded lullaby will be played through standard headphones at a controlled sound intensity of 35–45 dB, verified and adjusted prior to the intervention.
Category
Treatment - Other

3

Description
Control group: Headphones without Sound,Infants in this group will have standard headphones placed on their ears without any sound being played, from 10 minutes before until 10 minutes after the tracheal suctioning procedure. This is to provide the same environmental condition as the intervention groups while preventing the influence of external noise.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Mohammad Rahmanian
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Recruitment center
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Full name of responsible person
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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
Shiraz University of Medical Sciences
Proportion provided by this source
10
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of participants
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available