Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of recorded lullaby of father and mother on pain and some physiological indicators in arterial blood sampling of neonates admitted to neonatal intensive care units

Protocol summary

Study aim

Comparison of the effect of recorded parental lullaby on pain and some physiological indicators in arterial blood sampling of neonates admitted to neonatal intensive care units of hospitals affiliated to Shiraz University of Medical Sciences

Design

Clinical trial with control group, 51 infants were randomly assigned to three groups: father lullaby, mother lullaby and control group based on random block, 17 people in each group.

Settings and conduct

For 51 eligible infants, randomization is performed using a block of 4, three modes A, B and control. If the infant is in group A, first during blood sampling in addition to the usual methods of pain relief for 10 minutes The father receives the recorded lullaby through headphones, and in group B the same thing will happen using the mother's recorded lullaby. In the third group, only routine pain relief care will be provided.

Participants/Inclusion and exclusion criteria

Gestational age between 38 and 42 weeks Confirmation of the baby's hearing ability by the doctor Apgar in the normal range No sedative use by the baby during the previous 24 hours No substance abuse and sedative use by the mother No congenital anomalies No intracranial hemorrhage The baby should not be under mechanical ventilation and CPAP

Intervention groups

Receiving a recorded lullaby of parents (two groups) for 10 minutes during arterial blood sampling through headphones

Main outcome variables

Heart rate, Blood oxygen saturation and Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041101N4**
Registration date: **2022-04-18, 1401/01/29**
Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**
Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Majid Najafi Kalyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4251

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-11-06, 1401/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of recorded lullaby of father and mother on pain and some physiological indicators in arterial blood sampling of neonates admitted to neonatal intensive care units

Public title
Comparison of parental lullabies on pain and neonatal physiological parameters

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age between 38 and 42 weeks Confirmation of the baby's hearing ability by the doctor Apgar in the normal range No sedative use by the baby during the previous 24 hours No substance abuse and sedative use by the mother No congenital anomalies No intracranial hemorrhage The baby should not be under mechanical ventilation and CPAP

Exclusion criteria:
Reluctance of parents to cooperation Instability of physiological status in the infant

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

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **51**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible infants are randomly assigned to three groups of 17: father lullaby, mother lullaby, and control group, based on the four ABAB-BABA-ABBA-BAAB-AABB-BBAA blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
The research assistant and the evaluator of the results do not know in which intervention group the infants are. In this way, for the third group (control) to prevent the noise of the environment, headphones will be set without sound playback.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Schools of Nursing and Midwifery, Management and Medical Information science- - Shiraz University of

Street address
Zand

City
Shiraz

Province
Fars

Postal code
7193613119

Approval date
2021-12-18, 1400/09/27

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1400.064

Health conditions studied

1

Description of health condition studied
Neonates admitted to neonatal intensive care units

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain score

Timepoint
From ten minutes before to ten minutes after neonatal arterial blood sampling

Method of measurement
NIPS scale

2

Description
Heart rate

Timepoint
From ten minutes before to ten minutes after neonatal arterial blood sampling

Method of measurement
Baby heart rate monitoring

3

Description
Blood oxygen saturation

Timepoint
From ten minutes before to ten minutes after neonatal arterial blood sampling

Method of measurement
Pulseoximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Father lullaby. First, a lullaby that is sung to the fetus during pregnancy or is about to be sung to the baby will be recorded by the father and will be ready to play for 10 minutes during the blood draw. The recorded lullaby of the father with controlled decibels (35 to 45 decibels) will be played for ten minutes during arterial blood sampling through a headphone that is connected to a sound player and placed on the baby's ear.
Category
Behavior

2

Description
Intervention group2: Mother lullaby. First, a lullaby that is sung to the fetus during pregnancy or is about to be sung to her baby will be recorded by the mother and will be ready to play for 10 minutes during the blood draw. The recorded lullaby recorded by the mother in controlled decibels (35 to 45 decibels) will be played for ten minutes during arterial blood sampling through a headphone attached to an audio player and placed on the baby's ear.
Category
Behavior

3

Description
Control group: Control. For the control group, headphones will be set without sound to prevent ambient noise.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazee Hospital
Full name of responsible person
Dr. Ahmad Hossein Zadeh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Poost Foroosh
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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
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
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Roozegar
Position
Master student of critical care nursing
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Analyzed data can be shared after completion of the study as an article
When the data will become available and for how long
The access period will start 6 months after the results are published.
To whom data/document is available
All of the researchers in Medical Sciences Universities
Under which criteria data/document could be used
Analysis of data based on statistical software
From where data/document is obtainable
Dr. Majid Najafi Kalyani
What processes are involved for a request to access data/document
Sending request, permission from Ethic Committee, sending data
Comments