Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Hearing Simulated Intrauterine Sound on the Behavioral and Physiological Indicators of pain due to Blood Sampling in Preterm Infants

Protocol summary

Study aim
Determination the Effect of Hearing simulated intrauterine sound on the behavioral and physiological Indicators of pain due to blood sampling in preterm infant

Design
Clinical trial with control group,With parallel groups,design of 80 patients ,Double blind, randomized

Settings and conduct
Al-Zahra educational-thrapeutic Center of rasht city in Guilan University of Medical Sciences in Neonatal and Neonatal intensive care unit.

Participants/Inclusion and exclusion criteria
Premature infants aged 28 to 36 weeks, Weight less than 2500 grams,Chronological age less than a week,Physiological Stability (heart rate less than 160 beats per minute, less than 60 breaths per minute. Arterial oxygen saturation greater than 85%). First Minute apgar and fifth minute apgar ≥ 7,No history of intubation,No use of soothing or relaxing drug and anticonvulsant during the last 24 hours, Not having intraventricular hemorrhage or leukomalacia,The absence of any genetic abnormalities and any neurological disorder,Positive Moro Reflex

Intervention groups
In the intervention group, each newborn will listen to the sound for 5 minutes before sampling from heel , during and 5 minutes after the intervention. In the control group, the newborns will not receive any additional interventions during Sampling from the heel

Main outcome variables
Neonatal Pain Behavioral indicators, physiological indicators of Pain including heart rate and hemoglobin saturation from oxygen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190520043648N1**
Registration date: **2019-07-04, 1398/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-04, 1398/04/13**
Update count: **0**

Registration date
2019-07-04, 1398/04/13

Registrant information

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Moluk Pouralizadeh

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Hearing Simulated Intrauterine Sound on the Behavioral and Physiological Indicators of pain due to Blood Sampling in Preterm Infants

Public title

Effect of Hearing Simulated Intrauterine Sound on the Behavioral and Physiological Indicators of pain due to Blood Sampling in Preterm Infants

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Premature Infants Aged 28 to 36 Weeks Weight less than 2500 grams Chronological Age is Less than one Week Physiological Stability (heart rate less than 160 beats per minute, less than 60 breaths per minute. Arterial oxygen saturation greater than 85%) First Minute apgar and fifth minute apgar ≥ 7 more than 30 minutes passed from the last feed Positive Moro Reflex

Exclusion criteria:

History of intubation Use of analgesic or relaxing drugs and anticonvulsant during the last 24 hours Having intraventricular hemorrhage or leukomalacia Having any genetic abnormalities and any neurological disorder Shaking and touching the neonate during blood sampling by the mothers Within 4 hours before the intervention, any painful intervention or analgesic medication or other pharmacological or Non-pharmacological intervention has been performed Mother addiction The presence of any acute or chronic disease before or during pregnancy of the mother (such as heart disease and diabetes, preeclampsia, history of depression, etc.) Receiving any narcotic drug during and after delivery(In lactating mothers)

Age

From **1 day** old to **6 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Available samples are randomly assigned to two groups using the method of placing random blocks.In this way, the samples will be placed in one of the two intervention and control groups by random allocation method with four blocks.In this regard, it is initially assigned to the intervention group letter A and to control group the letter B.Then, 6 different modes, and the possibility of placing these two letters in blocks of four, including ABBA, ABAB, BAAB, BABA, BBAA, AABB, will be recorded in separate sheets. To create sequences after registering 6 different modes and possible, to place two letters A and B in the four blocks including ABBA, ABAB, BAAB, BABA, BBAA, AABB, and the placement of each letter in separate sheets, in the next step after the notes written inside a dish will be placed.Using a lottery, randomly, each time a sheet of paper is removed from the dish and the letters are written down accordingly, and the sheet is returned to the dish again.Frequency of the lottery will be 20 times according to the sample size of 80 neonates in two groups.Each time, the letters on the sheet are removed and will be added in the same order as the preceding letters.To create random allocation , the following software can also be used: Random allocation software . Next step ,in order to hide from the sealed envelopes will be used.In such a way that each of the designated letters,a number is assigned to the number of Specified sample size.The desired letter is placed inside an envelope and the number of that letter will be written on the envelope.The method of assigning samples to each intervention and control group is such that by selecting each neonate who has the criteria for entering the study, one of these envelopes is respectively the number on the envelope opened and the letter in the envelope indicates which neonate should be in which of the groups.Random allocation process will be conducted by one researcher who is not involved in the selection of participants and their assignment to the test group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant (neonate)does not know which of the two intervention or control groups belongs. In order to observe Blindness at the time of data analysis and the uncertainty of intervention and control groups during video record, it is done with a close-up of the face and body of the neonate.The purpose of this record is accurate and clear the movements of the face and limbs of the neonate.Note that the relevant sound player and loudspeaker device is not visible inside the film.And so the sound of the videos is also cut off after the record.At the end of the work, visiting the films and completing the checklist of behavioral and physiological indicators of pain will be done by one of the researchers who is not present at the time of sampling and does not know the random allocation and as well as the type of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Guilan University of Medical Sciences

Street address

Opposite the 17 Shahrivar hospital,shahid siadati street,Namjoo street

City

Rasht

Province
Guilan
Postal code
4193893345
Approval date
2019-05-11, 1398/02/21
Ethics committee reference number
IR.GUMS.REC.1398.070

Health conditions studied

1

Description of health condition studied
behavioral and physiological Indicators of pain
ICD-10 code
Z00.12
ICD-10 code description
Encounter for routine child health examination

Primary outcomes

1

Description
Pain level in the Neonatal Infant Pain Scale (NIPS) Behavioral checklist
Timepoint
The researcher will filming neonatal behavioral changes with a video camera each time for 1 minute in 3 steps, including 5 minutes before and after intervention, during which time (during blood sampling time) and 5 minutes after the completion of blood sampling.
Method of measurement
Neonatal Infant Pain Scale (NIPS) Behavioral checklist

Secondary outcomes

1

Description
Mean score of physiological indices including heart rate and hemoglobin saturation from oxygen
Timepoint
Each time for 1 minute in 3 steps including 5 minutes before and after the intervention, during it (during the bleeding time) and 5 minutes after the completion of blood sampling
Method of measurement
For measuring physiological parameters of pain including heart rate and hemoglobin saturation of oxygen, a calibrate pulse oximetry device, the model NOVAMETRIX will be used.

Intervention groups

1

Description
Intervention group:In the present study,Intrauterine simulated sound will be provided with medical educational software for intrauterine sound.This sound contains a relaxed Intrauterine sound simulated which is close to the real Intrauterine sounds. The intensity of the with a standard calibrated sound meter Device Benetech GM1351 will be adjusted to 45dB.The intervention method is that in the test group, each neonate will listen to this sound, 5 minutes before blood sampling, during and 5 minutes after intervention.The neonate will be in ancubator.And the temperature of the ancubator will be adjusted from 30 to 32 degrees.A portable speakers with external memory capacity of the TG 501 will be placed inside the ancubator.To perform blood sampling, the nurse disinfects the infant's limbs (the side of the foot) with alcohol cotton and uses a special needle for the premature infants.From the neonate inside the ancubator In supine position from the left side of the foot, blood sampling is done.
Category
Other

2

Description
Control group:The control group will receive the usual care
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra
Full name of responsible person
Shamimeh Yarahmadi
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Dr. Shadman Nemati
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opposite the 17 shahrivar hospital,shahid siadati street,namjoo street

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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Shamime Yarahmadi
Position
Bachelor of Nursing
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Bachelor
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Person responsible for updating data

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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
privacy of the data
Study Protocol
No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The research report will be sent to deputy of research and technology of Guilan University of Medical Sciences

When the data will become available and for how long

March 2020

To whom data/document is available

The managers of neonatal hospitals and the related policymakers

Under which criteria data/document could be used

Descriptive analysis

From where data/document is obtainable

To deputy of research and technology of Guilan University of Medical Sciences

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

To deputy of research and technology of Guilan University of Medical Sciences

Comments

This is a proposal in form of Master of science in nursing. thank you so much