Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of relaxing Voice and Tune voices using voice pillow on pain intensity of heel stick in hospitalized neonates

Protocol summary

Study aim

1- Determining the mean of heel hemorrhage pain severity in the control group newborns. 2- Determining the mean of heel hemorrhage pain severity in the Voice intervention group newborns. 3- Determining the mean of heel hemorrhage pain severity inTune intervention group newborns. 4. Make a comparison between the mean of heel hemorrhage pain severity in three groups.

Design

This study consists of two groups of intervention (Voice and Tune) and a control group, the initial selection of the samples is available and easy, and randomly (writing groups on the card and random selection of cards) in the target group. Total sample size are: 84 persons.

Settings and conduct

Sampling was carried out at the selected from hospitals affiliated to Isfahan University of Medical Sciences (Imam Hossein, Shahid Beheshti and Alzahra) and the sampling was done by the first fellow researcher and researcher during the filming of the neon, and the second collaborator researcher in The sampling stream does not scan videos with the eyes of the baby and blindness is done.

Participants/Inclusion and exclusion criteria

Babies admitted to selected hospitals of Isfahan University of Medical Sciences whose gestational age is 34 weeks and older and have a blood glucose check for parasite sampling.

Intervention groups

In the intervention group, the baby is sleeping on the pillow made by the researcher, and the song is played by the group and placed in the group for three minutes. In the control group, the baby is sleeping on the pillow and three minutes later, without music playing.

Main outcome variables

Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039844N1**
Registration date: **2018-07-03, 1397/04/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-03, 1397/04/12**
Update count: **0**

Registration date

2018-07-03, 1397/04/12

Registrant information

Name

Manijeh ربیعی فرادنبه

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-13, 1396/12/22

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of relaxing Voice and Tune voices using voice pillow on pain intensity of heel stick in hospitalized neonates

Public title
Effect of Voice and Tune in pain of neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Baby has a fetal age of 34 weeks and older The need for blood sampling from the heel There is no congenital anomaly in the form of cleft lip and palate The baby is not sleeping and is not crying Do not use a sedative or medication within 24 hours The baby has no hearing problem Failure to receive other painful procedure before intervention
Exclusion criteria:
Babies under 34 weeks No need to bleed from the heel There is a hearing problem Congenital malformation of the cleft lip and palate The baby is sleeping or crying Has received a home medicine within the last 24 hours
Age
From **238 days** old to **273 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Small cards are made up of the total volume of the sample, and they are written in the Voice group, the Tune intervention and the control group, each with the same number and the size of the sample size in each group. Then the cards are placed inside the box and, during the sampling, according to The card accident crashes out of the box and the newborn is placed in the same group and the cards are picked out of the box. This will continue until the entire card is removed from the box.
Blinding (investigator's opinion)
Double blinded
Blinding description
Simultaneously, by sampling the changes in the face and limb of the infant, a researcher colleague randomly assigned to the groups is filmed, and the films will be encoded by the first fellow of the researcher without specifying the intervention group or the control group. And the code is behind the card The second collaborator who does not group videos of newborns reviews the videos and evaluates them according to the Nips criteria. Then, the researcher will match the code with the code behind the cards, which determines which score is for which intervention group, and analyzes the data he is doing it.
Placebo
Not used
Assignment
Parallel
Other design features
In this study, audio pillows are used to play music, which is an innovation aspect and the pillow is designed to not damage the baby's ear, and with a sound level for babies of 35-40 dB that accurately measures this volume.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib street,isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.MUI.REC.1396.3.823

Health conditions studied

1

Description of health condition studied
Pain caused by neonatal blood sampling
ICD-10 code
Y84.7
ICD-10 code description
Blood-sampling as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Intensity of pain
Timepoint
3 minutes after playing voice or tune, through the pillow and in the control group 3 minutes after pillow sleep.
Method of measurement
Neonatal Infants Pain Scale

Secondary outcomes

1

Description
Score pain severity
Timepoint
3 minutes after the intervention
Method of measurement
Neonatal Infant Pain Scale

Intervention groups

1

Description
In the first intervention (voice group), the baby is sleeping on an acoustic pillow and a sedative vocal with specific sound intensity (35-40 dB) is distributed to the baby. Then, after 3 minutes, he takes blood from the baby and is filmed by a researcher fellow. The second co-worker examines films for the baby.
Category
Treatment - Devices

2

Description
Intervention group:(tune group): In the second intervention (the tune group), the baby is sleeping on an audio pillow and the sedative with a specific voice intensity (40-35 dB) is distributed to the baby. Then, 3 minutes later, he takes blood from the newborn and infants by the partner The researcher filmed and the second colleague of the researcher scores videos for the baby
Category
Treatment - Devices

3

Description
Category
empty

4

Description
Control group:The baby is sleeping on the audio pillow and without any intervention, after 3 minutes, the baby is taken from the infant and the baby is filmed by a researcher's colleague and the second co-worker is evaluating the films for the baby
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-zahra hospital
Full name of responsible person
Manijeh Rabiei
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shahnaz Kohan
Street address
Esfahan University of Medical Sciences, Hezar Jerib street
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Email
Kohan@nm.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Manijeh Rabiei
Position
student
Latest degree
Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
In this study, the score for neonatal pain is given on a neon film. Neonatal films are not shared, but the pain score will be shared in the intervention and control groups
When the data will become available and for how long
Get started 6 months after printing results
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to cite the results of data in research studies
From where data/document is obtainable
mrabiey1356@gmail.com
What processes are involved for a request to access data/document
The requestor can receive files within two weeks from sending emails through the introduction of his specifications by email and for which purpose he wants

to **Comments**