Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison effect of lullabies, Nurture voice and white voice on pain of during insert IV line in premature infants in neonatal intensive care unit

Protocol summary

Study aim

Comparison effect of lullabies, Nurture voice, and White sound on pain during insert IV line in premature infants.

Design

Four-arm parallel-group randomized trial with blinded outcome assessment of 110 premature infants. Randomization was done by using a card drawing from the envelope without replacement.

Settings and conduct

Hospitalized premature babies will be placed in four groups A, B, C, and D based on 4 blocks. In all 3 intervention groups, a sound selected based on randomization will be played from 5 minutes before the start of the insertion line, through a microphone with a frequency of 45-60 dB, which is placed at a distance of 20 cm from the baby's head, until 5 minutes after its completion. In the control group, the IV line will be performed without listening to any sound. The infant's pain will be measured three times: before, during, 5 minutes after.

Participants/Inclusion and exclusion criteria

Not giving sedatives during intravenous line insertion and at least 3 hours before; Not to have an underlying disease and extensive surgeries that cause pain (such as abdominal surgeries, etc.); Not to have paralyzing diseases and anatomical defects of limbs (hands and feet); No hearing impairment screening test confirmation); Apgar above five in the fifth minute after birth; The birth weight equal to or more than 1000 gr; Not having a chest tube; Having at least one experience of inserting an IV line

Intervention groups

The three intervening groups will listen to lullaby, nature sound, and white noise from 5 minutes before to 5 minutes after the end of the intravenous line placement. Control group: does not receive any intervention before, during, and after inserting the IV line.

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N12**
Registration date: **2023-10-21, 1402/07/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-21, 1402/07/29**
Update count: **0**

Registration date

2023-10-21, 1402/07/29

Registrant information

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Mahnaz Shoghi
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Iran university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison effect of lullabies, Nurture voice and white voice on pain of during insert IV line in premature infants in neonatal intensive care unit

Public title
Comparison effect of lullabies, Nurture voice and white voice on pain of during insert IV line in premature infants in neonatal intensive care unit.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Not receiving sedatives during intravenous line insertion and at least 3 hours before that Apgar above five in the fifth minute after birth Birth weight equal or more than 1000 gr

Exclusion criteria:
Diagnosis of hearing impairment (screening test confirmation) The presence of an underlying disease and extensive surgeries that cause pain (such as abdominal surgeries, etc.) Paralyzing diseases and anatomical defects of the limbs (hands and feet)

Age
From **28 days** old to **32 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Make four blocks A-B-C-D by drawing a card by the first mother. In each card, different states of the block are specified and the researcher will place 4 babies in the specified group respectively. The above card is taken out of the pocket and the mother of the 5th baby again takes out a card from the envelope and the status of the next group of 4 babies will be determined.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی ایران

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Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty

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Approval date
2023-11-01, 1402/08/10

Ethics committee reference number
IR.IUMS.REC.1402.276

Health conditions studied

1

Description of health condition studied
Pain during IV line insertion

ICD-10 code
R52.0

ICD-10 code description
R52.0

Primary outcomes

1

Description
Pain

Timepoint
Before inserting the IV line, during and 5 minutes after the completion of the inserting the IV line

Method of measurement
Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: listening to lullabies-lullabies will be played using an MP3 player and two tiny microphones placed on both sides of the baby's head at 20 cm. The sound broadcast in this intervention group started when the baby was transferred to the cut room and the baby's condition stabilized (about 5 minutes), and it will continue for 5 minutes after the end of the intervention.

Category
N/A

2

Description
Intervention group sound of nature- It will be played using an MP3 player and two tiny microphones placed on

both sides of the baby's head at 20 cm. The sound broadcast in this intervention group started when the baby was transferred to the cut room and the baby's condition stabilized (about 5 minutes), and it will continue for 5 minutes after the end of the intervention.

Category

N/A

3

Description

Intervention group 3: the Wight Voice- It will be played using an MP3 player and two tiny microphones placed on both sides of the baby's head at 20 cm. The sound broadcast in this intervention group started when the baby was transferred to the cut room and the baby's condition stabilized (about 5 minutes), and it will continue for 5 minutes after the end of the intervention.

Category

N/A

4

Description

Control group: In the control group, the intravenous line was inserted according to the usual routine without any additional intervention, only based on the usual care in the ward, and the pain of the baby will be recorded using the same tools at the same times as the other three groups (5 minutes before, during and 5 minutes after).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Sarem Hospital

Full name of responsible person
Dr. Nategh

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End of phaze3- Ekbatan Town, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mahnaz Shoghi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After Data coding in order to keep the confidentiality of the participants in the research

When the data will become available and for how long
The end of sampling till six months after the article publishing.

To whom data/document is available
Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used
Systematic review and meta-analysis or secondary analysis citation

From where data/document is obtainable
Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

What processes are involved for a request to access data/document
After sending a request to the academic email, we will send our data files for up to one week.

Comments