

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

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

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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

Street address

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

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Postal code

1996713883

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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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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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