Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Studying the effect of light and sound stimulus modulation on pain caused by venous blood sampling in premature infants admitted to the neonatal intensive care unit.

Protocol summary

Study aim
Studying the effect of light and sound stimulus modulation on pain caused by venous blood sampling in premature infants admitted to the neonatal intensive care unit.

Design
A controlled clinical trial with parallel groups, consisting of two intervention groups and a control group, will be conducted in a randomized on 90 infants. Non-random sampling of the "available" type will be used to enter the study. They will be divided into three intervention groups: A, B, and a control group, using the random block method, using the site http://www.graphpad.com/quickcalcs/index.cfm.

Settings and conduct
In this study, 90 newborns with a gestational age of 28 to 32 weeks will be enrolled based on the newborn's medical records and admitted to the intensive care unit of Imam Khomeini Hospital in Dargaz. Blinding will not be performed in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: parental consent to participate in the intervention; preterm infant from 32 to 37 weeks according to the record. Exclusion criteria: use of analgesics and sleeping pills in the past 24 hours; infant Apgar score less than 6.

Intervention groups
In this study, we will have two intervention groups and a control group. The first intervention group: to modify the sound stimulus, an earplug will be placed on the infant 15 minutes before the procedure and will remain until 15 minutes after the procedure. The second intervention group: to modify the light stimulus, an eye mask will be placed over the infant's eyes 15 minutes before the procedure and will be removed 15 minutes after the blood draw. The control group: routine care will be provided during the blood draw.

Main outcome variables
Crying duration; Pain intensity

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211211053351N4**
Registration date: **2025-06-12, 1404/03/22**
Registration timing: **prospective**

Last update: **2025-06-12, 1404/03/22**
Update count: **0**
Registration date
2025-06-12, 1404/03/22

Registrant information
Name
sadeghi tahereh
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-07-01, 1404/04/10
Expected recruitment end date
2025-09-21, 1404/06/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of light and sound stimulus modulation on pain caused by venous blood sampling in premature infants admitted to the neonatal intensive care unit.

Public title

Study of light and sound stimuli on pain in newborns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns with a gestational age of 28 to 32 weeks Newborn hospitalization Needing venous blood sampling

Exclusion criteria:

The infant's 5-minute Apgar score less than 6 Use of sedatives and hypnotics in the past 24 hours Failed to obtain a vein during the first injection

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method was utilized for allocating samples to two groups. To generate the random sequences, we used the website http://www.graphpad.com/quickcalcs/index.cfm. We employed six types of four-pair blocks as follows: AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5), and BAAB (6). Thus, the allocation of samples to the two groups was carried out using the block randomization method, which helps enhance balance and reduce bias in the selection of samples.

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

Research Ethics Committees of School of Nursing & Midwifery - Mashhad University of Medical Sciences

Street address

Nursing and Midwifery School , Shahid Dr. Kharazmi Educational Building, University Campus, East Gate ofFerdowsi University of Mashhad, Azadi Square

City

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Province

Razavi Khorasan

Postal code

9137913199

Approval date

2024-03-05, 1402/12/15

Ethics committee reference number

IR.MUMS.NURSE.REC.1403.004

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Duration of baby's crying after opening an IV line

Timepoint

Immediately after injection

Method of measurement

By means of a timer

2

Description

Neonatal pain scale

Timepoint

During injection, after injection

Method of measurement

The Neonatal Pain, Agitation and Sedation Scale (N-PASS): is used to assess pain, agitation, and sedation in neonates. It consists of two scales: a pain/agitation scale and a sedation scale. The pain/agitation scale ranges from 0 to 10, with higher scores indicating greater pain or agitation. The sedation scale ranges from 0 to -10, with lower scores indicating deeper sedation.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To adjust the sound stimulus, an earmuff will be placed on the infant 15 minutes before the procedure and will remain on for 15 minutes after the procedure.
Category
Treatment - Other

2

Description
Intervention group: To adjust the sound stimulus, an earmuff will be placed on the infant's eye 15 minutes before the procedure and will remain on for 15 minutes after the procedure.
Category
Treatment - Other

3

Description
Control group: First, the injection site will be identified, cleaned with alcohol, and the catheter will be inserted.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dargaz Imam Khomeini Hospital, Razavi Khorasan Province
Full name of responsible person
Tahereh Sadeghi
Street address
Nursing and Midwifery School , Shahid Dr. Kharazmi Educational Building, University Campus, East Gate ofFerdowsi University of Mashhad, Azadi Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Research and Technology Deputy- Ghorashi Building- Next to Hoveyzeh Cinema- Daneshgah Street- Mashhad, Razavi Khorasan
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Grant name
University grant
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Tahereh sadeghi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable