Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effectiveness of white noise and the absence of white noise on pain intensity during airway suctioning in premature infants admitted to the neonatal intensive care unit

Protocol summary

Study aim
Investigating the effect of white noise on pain during airway suctioning of premature babies admitted to the neonatal intensive care unit

Design
A controlled, parallel-group, unblinded, non-randomized, phase 3 clinical trial of 44 patients.

Settings and conduct
The study will be conducted without blinding in the neonatal intensive care unit of Beheshti Hospital in Isfahan. Eligible patients will be assigned non-randomly to either an intervention group or the control group and will receive their respective intervention.

Participants/Inclusion and exclusion criteria
Major inclusion criteria: Placement in an incubator for at least three days; fifth minute Apgar score of 7 or higher; and weight above 1500 grams. Major exclusion criteria: Congenital abnormality; history of alcohol or drug use by the mother; and hearing impairment.

Intervention groups
From five minutes before suctioning begins to ten minutes after, infants in the intervention group listen to white noise at 45-60 dB through MP3-connected headphones. In the control group, no music will be played for babies.

Main outcome variables
Pain intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221213056807N1**
Registration date: **2023-09-20, 1402/06/29**
Registration timing: **prospective**
Last update: **2023-09-20, 1402/06/29**
Update count: **0**

Registration date
2023-09-20, 1402/06/29

Registrant information

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Saeide Aria
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-07, 1402/07/15

Expected recruitment end date
2023-11-06, 1402/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of white noise and the absence of white noise on pain intensity during airway suctioning in premature infants admitted to the neonatal intensive care unit

Public title
Effect of white noise on pain intensity during airway suctioning

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Placement in an incubator for a minimum of three days A five-minute Apgar score of 7 or higher Wieght above 1500 grams Age between 3 and 28 days
Exclusion criteria:
Congenital malformation (heart disease, hydrocephalus, etc.) A history of alcohol or drug use by the mother Hearing impairment Presence of acute diseases (sepsis, necrotizing enterocolitis, asphyxia, or acute respiratory problems) Strong response to sound stimuli such as screaming, crying, and struggling Painkillers received in the last 48 hours
Age
From **3 days** old to **28 days** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Ethics Committee of Kerman University of Medical Scicences
Street address
Haft-Bagh Alavi Ave.
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Province
Kerman
Postal code
7616913555
Approval date
2023-07-31, 1402/05/09
Ethics committee reference number
IR.KMU.REC.1402.147

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain intensity
Timepoint
10 minutes before, during, and 10 minutes after the intervention
Method of measurement
Neonatal Infant Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: From five minutes before suctioning begins to ten minutes after, infants in the intervention group listen to white noise at 45-60 dB through MP3-connected headphones.
Category
Other

2

Description
Control group: In the control group, no music will be played for babies.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Saeide Aria
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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Dr. Abedin Iranpour
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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
Kerman 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
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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
Deidentified Individual Participant Data Set
When the data will become available and for how long
After the article extracted from the project is published and for six months
To whom data/document is available
Researchers
Under which criteria data/document could be used
For research purposes
From where data/document is obtainable
Email to the corresponding author
What processes are involved for a request to access data/document
Personal email to saeidearia71@gmail.com
Comments