

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

Name

Saeide Aria

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 2063

Email address

saeide.aria71@gmail.com

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 Weight 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 Sciences

Street address

Haft-Bagh Alavi Ave.

City

Kerman

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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Motahhari Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Abedin Iranpour
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Email
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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

Name of organization / entity
Kerman University of Medical Sciences
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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

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