Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of lullabies on some physiologic and behavioral responses during endotracheal suctioning in premature neonates in neonatal intensive care unit in a Shiraz Medical Sciences University hospital.

Protocol summary

Summary

1)Objectives: Determining the effect of lullabies on some physiologic and behavioral responses during endotracheal suctioning in premature infants in neonatal intensive care unit. 2) Design: Single-blind randomized clinical trial 3) Setting and conduct: 25 infants qualified for the study are randomly assigned to A and B groups by using the sealed envelope method. The lullaby is played for the babies in group A before and after the suctioning and then it will not be played for the next 24 hours. The order is reversed for the babies in group B. In both groups,the babies are filmed for 20 minutes and heart rate, blood oxygen saturation and behavioral states are recorded by APIB scale. Finally, the changes in the physiological and behavioral parameters of the two groups are compared. 4) Participants including major eligibility criteria: Postnatal age 1 to 28 days after birth; gestational age 28 to 36 weeks; neonate's need to endotracheal suctioning; no sedative medicine use during the past 24 hours; no maternal drug or sedative abuse; neonatal hearing ability (having startle reflex); no congenital malformation; no evidence of grade II or higher intraventricular hemorrhage or neurological disorders; not having used invasive procedures for the baby for at least 3 hours; endotracheal tube insertion at least 24 hours earlier. Major exclusion criteria: Parents' unwillingness to continue cooperating in research; symptoms of physiological instability in the infant. 5) Interventions: Playing lullaby before and after the suctioning 6) Main outcome measures (variables): Heart rate, blood oxygen saturation, and behavioral responses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121124037N2**

Registration date: **2017-05-18, 1396/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-18, 1396/02/28

Registrant information

Name

Zahra Zahadatpour

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of lullabies on some physiologic and

behavioral responses during endotracheal suctioning in premature neonates in neonatal intensive care unit in a Shiraz Medical Sciences University hospital.

Public title
The effect of lullabies on physiological and behavioral parameters among the preterm neonates
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Postnatal age 1 to 28 days after birth; gestational age 28 to 36 weeks; neonate's need to endotracheal suctioning; no sedative medicine use during the past 24 hours; no maternal drug or sedative abuse; neonatal hearing ability (having startle reflex); no congenital malformation; no evidence of grade II or higher intraventricular hemorrhage or neurological disorders; not having used invasive procedures for the baby for at least 3 hours; endotracheal tube insertion at least 24 hours earlier. Exclusion criteria: Parents' unwillingness to continue cooperating in research; symptoms of physiological instability in the infant;having Heart disease; Pneumothorax
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **25**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Sealed envelope method randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
Postal code
Approval date
2015-08-24, 1394/06/02
Ethics committee reference number
IR.SUMS.REC.1394.92

Health conditions studied

1

Description of health condition studied
preterm infant
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Heart rate
Timepoint
from 10 minutes before suctioning until 10 minutes after suctioning
Method of measurement
Pulse oxymeter

2

Description
Blood oxygen saturation
Timepoint
from 10 minutes before suctioning until 10 minutes after suctioning
Method of measurement
Pulse oxymeter

3

Description
Behavioral responses.
Timepoint
from 10 minutes before suctioning until 10 minutes after suctioning
Method of measurement
APIB scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: at first receiving lullabies and after 24 hours receiving headphones without playing lullabies
Category

Prevention

2

Description
Control group:at first receiving headphones without playing lullabies and after 24 hours receiving lullabies
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zeinab Hospital
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Shiraz University of Medical Sciences, Zand Street, Shiraz
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences, Hazrat-e-Fatemeh Nursing and Midwifery Faculty
Full name of responsible person
Zahra Zahadatpour
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty