

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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)

###### Phone

+98 71 3720 2096

###### Email address

zahadatpour@sums.ac.ir

##### 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

#### Position

Neonatal Intensive Care Nursing Master of Science Student

#### Other areas of specialty/work

#### Street address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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Pediatric Nursing MS, Faculty member

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## Person responsible for updating data

### Contact

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#### Full name of responsible person

Zahra Zahadatpour

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**Web page address**

## 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*