

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparing the effect of music and mother`s lullaby on physiological responses and sleep of preterm infants in NICU

Protocol summary

Study aim

the effect of music and mother's lullaby on physiological responses and sleep of preterm infants

Design

Clinical trial with control group, with parallel groups, without blinding

Settings and conduct

The researcher will refer to Ali ebn Abitaleb hospital and then the sample according to inclusion criteria will be divided to three homogeneous groups. Intervention will perform for each group once a day for 14 days. Physiological responses will be documented 10 min before intervention, during intervention and 20 min after intervention and sleep status will record on first day of intervention and 14th day.

Participants/Inclusion and exclusion criteria

inclusion criteria: Infants with gestational age more than 30 weeks, infants without congenital anomalies

Intervention groups

Intervention group1: they shall be held in their mother's tender embrace and recorded lullaby in Persian will play for 20 min for them. Intervention group2: they shall be held in their mother's tender embrace and mother will sing for 20 min for them. Control group: they shall be held in their mother's tender embrace without any intervention for 20 min.

Main outcome variables

Physiological responses, Sleep

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216042011N1**

Registration date: **2019-02-15, 1397/11/26**

Registration timing: **prospective**

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

monirsadat nematollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of music and mother`s lullaby on physiological responses and sleep of preterm infants in NICU

Public title

Comparing the effect of music and mother`s lullaby on physiological responses and sleep of preterm infants

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age more than 30 weeks
Lack of congenital anomalies
Lack of mechanical ventilation

Exclusion criteria:

having hear difficulties receive sedatives three hours before intervention

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample will be selected from preterm infants according to inclusion criteria, then by using of random numbers table, infants will be placed in three groups. On Saturdays and Sundays, eligible babies will be placed in recording mother's lullaby group, on Mondays and Tuesdays will be placed in live mother's lullaby group, and on Wednesdays and Thursdays, the baby will not be subjected to any intervention.

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

,Medical University Campus,Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-11-13, 1397/08/22

Ethics committee reference number

IR.KMU.REC.1397.269

Health conditions studied**1****Description of health condition studied**

Physiological responses

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Arterial oxygen saturation

Timepoint

Before, during and after intervention

Method of measurement

Pulseoximetry

2**Description**

sleep

Timepoint

The first and the 14th day of intervention

Method of measurement

BISQ questionnaire

3**Description**

heart rate

Timepoint

Before, during and after intervention

Method of measurement

Cardiopulmonary Monitoring

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1:The First intervention group shall be held in their mother's tender embrace and by using the headphones, the recorded lullaby sounds in Persian will be set for twenty minutes every evening. Physiologic responses of infants will be documented in check list 10 min before intervention, during intervention and 20 min after intervention. for evaluating the baby's sleep status, researcher will be completed the sleep questionnaire on the first day of intervention and the 14th day. Intervention will be performed once a day for 14 days.

Category

Other

2

Description

Intervention group 2: The second intervention group shall be held in their mother's tender embrace and the mother will sing lullaby for twenty minutes. Physiologic responses of infants will be documented in check list 10 min before intervention, during intervention and 20 min after intervention. For evaluating the baby's sleep status, researcher will be completed the sleep questionnaire on the first day of intervention and the 14th day. Intervention will be performed once a day for 14 days.

Category

Other

3

Description

Control group: In this group, infant shall be held in their mother's tender embrace for 20 min without playing music for them. Physiologic responses of infants will be documented in check list 10 min before intervention, during intervention and 20 min after intervention. For evaluating the baby's sleep status, researcher will be completed the sleep questionnaire on the first day of intervention and the 14th day. Intervention will be performed once a day for 14 days.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebne Abitaleb

Full name of responsible person

monirsadat Nematollahi

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Hazrat Ali ebn Abitaleb hospital, Mofateh Blvd.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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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

Full name of responsible person

Monirsadat Nematollahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

relied on secrecy

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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