Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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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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
Pulseoximetery

2

Description
sleep

Timepoint
The first and the 14th day of intervention

Method of measurement
BISQ questionnare

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
Reza Dehnaviyeh

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http://kmu.ac.ir

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 updating data

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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