Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparing the lilt voice of Quran with normal situation, silence, and lullaby music on physiological responses and behavioral measures of premature infant discharged from neonatal intensive care unit

Protocol summary

Summary

Objective: this research planed to compare the effects of holly Quran recitation, with normal situation, silence and lullaby music on physiological responses and behavioral measures of premature infants. Design: a double blind randomized controlled trial will conducted to compair the effects of holly Quran recitation, normal situation, silence, and lullaby music on preterm newborns. All preterm newborns will randomly allocated to either the experimental or control group. Procedure: 120 premature infants who have inclusion criteria of this study, will randomly allocated in four groups: holly Quran recitation, silence, lullaby music and control groups. They will be observed for four dependent variables; oxygen saturation levels, heart rate, respiration rate and behavioral state. Interventions include; 20 minutes Holly Quran recitation (verse 7-23 of Yusuf Quranic chapters, by Shahhat Mohammad Anvar sound) and lullaby music(good night little, the sound of the Islamic Republic of Iran Radio) that will played via headphone with volume range 50-60 dB. Headphone with no sound will be used for silence group. Any group will be observed for physiological responses and behavioral state from 10 minutes before to 30 minutes after intervention and recorded numerous at 5,10 minutes before and 5, 10, 15, 20, 25 and 30 minutes after beginning of intervention, will be used to analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110097746N1**
Registration date: **2011-10-31, 1390/08/09**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-10-31, 1390/08/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-05-20, 1391/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the lilt voice of Quran with normal situation, silence, and lullaby music on physiological responses and behavioral measures of premature infant discharged from neonatal intensive care unit

Public title

Comparing the lilt voice of Quran with normal situation,

silence, and lullaby music on physiological responses and behavioral measures of premature infant

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: 1- Gestational age 28 to 37 weeks 2- Appropriate-for-gestational-age (AGA) 3- APGAR scores from 7 to 10 at one and five minutes after birth 4- Hearing confirmed by OAE 5- Iranian neonate 6- Nutrition by mother milk 7- No current phototherapy 8- No morbidities such as congenital defects, intraventricular hemorrhage (IVH), necrotizing enterocolitis (NEC), sepsis, acute lung disease or neonatal anemia and any acute illness 9- No undergoing mechanical ventilation 10- No receiving sedation medications such as Phenobarbital 11- No documentation of hyper responsiveness to the sound and 12- No history of maternal drug abuse, including alcohol or illegal substances. Only infants, who are clinically stable and physically able to tolerate the stimuli will be included. Exclusion criterias: signs of hyper responsiveness to the sound such as hiccup, facial grimace, finger splay, clenched fingers, crying, vomiting, and heart rate over 200; oxygen saturation lower than 80 and any need to handling.

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qom University of Medical Sciences

Street address
Shahid Lavasani street

City
Qom

Postal code

Approval date
2011-10-02, 1390/07/10

Ethics committee reference number
پ/34/12078

Health conditions studied

1

Description of health condition studied
physiologic and behavioral state

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Oxygen saturation

Timepoint
Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement
Monitor

2

Description
Respiratory rate

Timepoint
Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement
Monitor

3

Description
Heart rate

Timepoint
Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement
Monitor

4

Description
Behavioral state

Timepoint
Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

Method of measurement
Behavioral state instrument scale

Secondary outcomes

empty

Intervention groups

1

Description
4- Control group: natural situation: neonates in this group will recive no intervention and only will observed for dependent variables for 40 minutes
Category
Treatment - Other

2

Description
1- Holly Quran recitation group:the intervention in this group will include 20 minutes recitation of Yusuf Quranic chapters, verse 7-23, by Shahhat Mohammad Anvar sound that will played via headphone by volume range 50-60 dB
Category
Treatment - Other

3

Description
3- Silence gruop: headphone with no sound will placed on their ear for 20 minutes
Category
Treatment - Other

4

Description
2- Lullaby music group: lullaby music (good night little, the work of the Islamic Republic of Iran radio) include 20 minutes music, will played via headphone by volume range 50-60 dB for this group
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Izadi Medical Center
Full name of responsible person
Street address
City
Qom

2

Recruitment center
Name of recruitment center
Hazrate Zahra Medical Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences
Full name of responsible person
Ms. Naiieri
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Shahid Lavasani street
City
Qom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom 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
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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