

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 planned 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 compare 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

###### Name

Narges Eskandari

###### Name of organization / entity

Azad Islamic University, Khalkhal branch

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 1770 3301

###### Email address

eskandari.2008@yahoo.com

##### 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**

34/12078/پ

**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 receive no intervention and only will be 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 be played via headphones by volume range 50-60 dB

#### Category

Treatment - Other

### 3

#### Description

3- Silence group: headphones with no sound will be placed on their ears 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 be played via headphones 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

##### Street address

##### City

Qom

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qom University of Medical Sciences

##### Full name of responsible person

Ms. Naiieri

##### Street address

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

##### Name of organization / entity

Azad Islamic University, Khalkhal branch

##### Full name of responsible person

Narges Eskandari

##### Position

Senior lecturer

##### Other areas of specialty/work

##### Street address

Valieasr street

##### City

Khalkhal

##### Postal code

##### Phone

+98 25 1770 3301

##### Fax

##### Email

eskandari.2008@yahoo.com;

narges.eskandari@iran.ir;

narges.eskandari@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Azad Islamic University, Khalkhal branch

**Full name of responsible person**

Narges Eskandari

**Position**

M.Sc in midwifery

**Other areas of specialty/work****Street address**

Number 98, 69th Aveniu, Talegani Street

**City**

Qom

**Postal code****Phone**

+98 25 1770 3301

**Fax****Email**

eskandari.2008@yahoo.com;

narges.eskandari@iran.ir;

narges.eskandari@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Narges Eskandari

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone****Fax****Email**

eskandari.2008@yahoo.comnarges.eskandari@iran.ir

narges.eskandari@gmail.com

**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*