

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Protocol summary

Summary

Background: Investigators have demonstrated that providing appropriate complementary and alternative therapy is necessary to developmental outcomes in preterm infants and pleasant sound of holly Quran recitation can be used as a useful and effective procedure to decrease the anxiety and affects on physiological and neurobehavioral functioning in patients. The aim of this research is to study effects of holly Quran recitation on physiological responses in premature infants. Materials and methods: In a double blind randomized control trail, 120 premature infants who will be admitted to the NICU of Shahid Akbarabadi hospital in Tehran, and have inclusion criteria of this study, will randomly assigned to two groups: control group and holly Quran recitation group, and will be observed for three dependent variables; oxygen saturation levels, heart rate and respiration rate. Intervention will be including 20 minutes recitation of Yusuf Quranic chapters, by Shahhat Mohammad Anvar sound that will be played for experimental group via headphone on the morning shift. The volume range will be 50-60 db. Two groups will be observed by monitor for physiological responses from 10 minutes before to 10 minutes after intervention and will be recorded before and 10,20,30 minutes after the beginning of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806172324N3**
Registration date: **2010-06-24, 1389/04/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-24, 1389/04/03

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

School of Nursing and Midwifery, Iran University of Medical Sciences

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2009-09-21, 1388/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Public title

The Effect of Holly Quran Recitation on physiologic responses of premature infants in neonatal intensive care unit, Shahid Akbarabadi treatment & education center, 2009

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Iranian neonate with gestational age 28-36 weeks, birth weight over 1500 gr, 1 and 5-minute APGAR scores from 7 to 10, breast feeding, hearing confirmed by startle reflex, no documentation of hyper responsiveness to the sound, clinically stable infant that are appropriate for gestational age (AGA) and having no operative delivery, anomalies associated with neurological problems, undergoing mechanical ventilation, phototherapy, congenital abnormalities, symptomatic sepsis, acute illness, intraventricular hemorrhage, receiving medications such as Phenobarbital or oxygen and history of drug abuse in mother. Exclusion criteria: hyper responsiveness to the music such as hiccup, facial grimace, finger splay, clenched fingers, crying, vomiting, and heart rate over 200 per min, oxygen saturation lower than 80%, any need to handling or nursing intervention and difficulty in recording of physiological responses.

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

School of Nursing and Midwifery, Iran University of Medical Sciences

Street address

School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave, P.P.

Box: 19395-4798

City

Tehran

Postal code

19964

Approval date

empty

Ethics committee reference number

1323577

Health conditions studied

1

Description of health condition studied

physiologic responses of premature infants

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

improving in physiologic responses of premature infants

Timepoint

every 10 minute

Method of measurement

by monitor

Secondary outcomes

empty

Intervention groups

1

Description

Holly Quran Recitation

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi treatment & education center

Full name of responsible person

Maryam Keshavarz

Street address

Molavi Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

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School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave

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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

School of Nursing and Midwifery, Iran 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

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

MSc in midwifery - academic member

Other areas of specialty/work

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Email

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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