

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Iran (Islamic Republic of)

Phone

+98 21 4365 1813

Email address

keshavarz@iums.ac.ir

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		Box: 19395-4798
Purpose	Supportive	City Tehran
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.	Postal code 19964
Age	To 1 year old	Approval date empty
Gender	Both	Ethics committee reference number 1323577
Phase	N/A	Health conditions studied
Groups that have been masked	No information	<u>1</u>
Sample size	Target sample size: 120	Description of health condition studied physiologic responses of premature infants
Randomization (investigator's opinion)	Randomized	ICD-10 code P07.3
Randomization description		ICD-10 code description Other preterm infants
Blinding (investigator's opinion)	Double blinded	Primary outcomes
Blinding description		<u>1</u>
Placebo	Not used	Description improving in physiologic responses of premature infants
Assignment	Parallel	Timepoint every 10 minute
Other design features		Method of measurement by monitor
Secondary Ids	empty	Secondary outcomes empty
Ethics committees		Intervention groups
<u>1</u>		<u>1</u>
Ethics committee		Description Holly Quran Recitation
Name of ethics committee	School of Nursing and Midwifery, Iran University of Medical Sciences	Category Other
Street address	School of Nursing and Midwifery, Iran University of Medical Sciences, Rashid Yasami St. Valiasr Ave, P.P.	Recruitment centers
		<u>1</u>
		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

Street address

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

City

Tehran

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

Street address

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

City

Tehran

Postal code

19964

Phone

+98 21 8247 1406

Fax

+98 21 8879 3805

Email

keshavarz@iums.ac.ir , m_keshir@yahoo.com

Web page address

Person responsible for scientific 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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+98 21 8247 1406

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+98 21 8879 3805

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Keshavarz@iums.ac.ir , m_keshir@yahoo.com

Web page address

Person responsible for updating data

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School of Nursing and Midwifery, Iran University of Medical Sciences

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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