

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect Voice of the Holy Quran on the duration of transition from gavage to first oral feeding and vital signs at premature newborns hospitalized in neonatal intensive care unit

Protocol summary

Study aim

The effect of listening to the holy quran on the physiological responses of premature infants admitted to the neonatal intensive care unit

Design

Premature infants with inclusion criteria were randomly assigned to control and intervention groups

Settings and conduct

The play of Quranic voices for preterm infants will be performed in the neonatal intensive care unit.

Participants/Inclusion and exclusion criteria

1. Gestational age less than 32 weeks 2. Physiological stability over the last 24 hours 3. Birth weight proportional to the gestational age 4. The APGAR score of 7 and more in the first and fifth minutes of birth 5. Lack of family history of deafness or mental retardation 6. Non-underlying disease 7. Getting full breastfeeding or formula through oral gavage and oral feeding 8. Lack of disease, except premature 9. Being Muslim Exclusion criteria 1-Abnormal physiological responses 2-Neonatal need for any medical intervention 3-Impairment in infant's consciousness 4-Incidence of digestive problems such as necrotizing enterocolitis 5-Unwillingness of the infant's parents

Intervention groups

Playing Quranic Voice for Intervention Group Do not distribute the Quran to the control group

Main outcome variables

Improve vital signs Reduce the feeding time of the gavage

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20170620034653N3**

Registration date: **2018-06-19, 1397/03/29**

Registration timing: **retrospective**

Last update: **2018-06-19, 1397/03/29**

Update count: **0**

Registration date

2018-06-19, 1397/03/29

Registrant information

Name

Zahra Tayebi Myaneh

Name of organization / entity

Qazvin University of medical science

Country

Iran (Islamic Republic of)

Phone

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Email address

z.tayebi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect Voice of the Holy Quran on the duration of transition from gavage to first oral feeding and vital

signe at premature newborns hospitalized in neonatal intensive care unit

Public title

The effect of the Quran's voice on the formation of oral nutrition in premature infants admitted to the intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age less than 32 weeks Physiological stability over the last 24 hours The APGAR score of 7 and more in the first and fifth minutes of birth Getting full breastfeeding or formula through oral gavage and oral feeding Lack of disease, except premature Being Muslim Lack of family history of deafness or mental retardation

Exclusion criteria:

Abnormal physiological responses Unwillingness of the infant's parents Incidence of digestive problems such as necrotizing enterocolitis Neonatal need for any medical intervention Impairment in infant's consciousness

Age

From **1 day** old to **2 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Easy sampling will be done. After selecting samples, their random assignment will be done in two groups using the card method inside the bag.

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

esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Shahid Bahonar Blvd., Qazvin, Iran. Iran

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Isfahan

Postal code

14756-33641

Approval date

2015-05-22, 1394/03/01

Ethics committee reference number

IR.mui.REC.1394.3.470

Health conditions studied

1

Description of health condition studied

Duration of feeding from gavage to first oral nutrition in premature infants

ICD-10 code

p07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description

Vital Signs - Duration of the passage from feeding to the tube to oral feeding-weighing

Timepoint

Physiological responses including heart rate, respiratory rate, arterial oxygen saturation, mean arterial pressure and temperature were recorded in three stages, every 10 minutes; immediately before the intervention, during the intervention (minutes 10 and 20 after intervention) And 10 minutes after the end of the intervention.

Method of measurement

Using a monitoring device

Secondary outcomes

1

Description

Weight gain in premature baby

Timepoint

The completion time of the study

Method of measurement

Weighing using scales

Intervention groups

1

Description

Intervention group: The Voice of the Holy Qur'an was performed at 45 dB for 20 minutes at three times before feeding at first, middle and end of the evening shift, and after that, the nutrition begins. This is done until the

baby reaches her first full oral feeding.

Category

Rehabilitation

2

Description

Control group: Premature babies who do not hear the Quran's voice

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz Educational and treatment center (NICU)

Full name of responsible person

Zahra Tayebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Zahra Tayebi Myaneh

Position

دانشجوی پرستاری

Latest degree

Master

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/documentDetails of the data are published in the form of
demographic information in the article**When the data will become available and for how long**

Immediately after the publication of the article

To whom data/document is available

There is no limit

Under which criteria data/document could be usedData will be available for reference and use in other
studies.**From where data/document is obtainable**

Send the email to the responsible author

What processes are involved for a request to access data/document

Send the email to the responsible author

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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