

# 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

+98 28 3224 8614

###### 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

#### City

Esfahan

#### Province

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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Alborz Hospital, Valiasr Street, Karaj

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Amir Pymani

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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**

Nursery

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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/document**Details 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 used**Data 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

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