

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

#### Protocol summary

##### Summary

The current research is a clinical trial study, in which samples were selected using nonprobability purposive convenience sampling method, divided into 3 groups and enrolled into the study based on inclusion criteria. In this study, 75 infants with 48 hours old and gestational age between 28 to 34 weeks hospitalized in neonatal intensive care unit at Imam Reza and Omolbanin Hospitals in Mashhad, Iran, in addition to routine care, received recorded sound of mother's heartbeats twice a day for eight consecutive days. The infants in control group received routine care and silent headphones for 40 minutes. The infants in intervention group received recorded sound of mother's heartbeats for 20 minutes in addition to routine cares. The placebo group listened to the recorded sound of another person's heartbeats for 20 minutes. Each intervention for all three groups included a forty-minute period. The first ten minutes involved baseline measurements prior to playing the sound. In the second and third ten minutes, recorded sound of mother's heartbeats was played for the intervention and placebo groups. Finally, the sound was stopped and the related measurements were performed after playing the recorded sound in the fourth ten minutes. Data collected in each intervention included oxygen saturation percentage, heartbeat per minute, respiratory rate per five minutes and duration of deep sleep after playing the sound. An expert did infant hearing screening after discharge.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016080629210N1**

Registration date: **2016-12-19, 1395/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-19, 1395/09/29

##### Registrant information

###### Name

Zahra Yazdani

###### Name of organization / entity

School of Nursing and Midwifery, Mashhad

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3859 1511

###### Email address

yazdaniz931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University Of Medical Sciences

##### Expected recruitment start date

2016-05-17, 1395/02/28

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

##### Public title

The effect of recorded maternal heart rate on sleep and Physiological Parameters in preterm infants.

##### Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: the infant must have spontaneous breathing and needs no mechanical ventilation; parents should be willing and consent to participate in the study; birth weight over 1000 g , no congenital abnormalities; lack of hearing problems in newborns; 28 to 34 weeks of gestational age; lack of clear infection; no maternal addiction. Exclusion criteria: need for assisted mechanical ventilation during the intervention; unwillingness of parents to continue to participate in the project; Grade 3 and 4 intraventricular hemorrhage; history of alcohol and coffee consumption; successive apnea; incidence of seizures in newborns; hearing problems; intrauterine growth restriction (IUGR); anemia with hemoglobin  $\leq 10$  g/dL (hemoglobin less or equal to 10 grams per deciliter)

### Age

From **7 months** old to **8 months** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **75**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee Of Mashhad University Of Medical Science

##### Street address

Daneshgah Street

##### City

mashhad

##### Postal code

#### Approval date

2016-05-09, 1395/02/20

#### Ethics committee reference number

IR.MUMS.REC.1395.72

## Health conditions studied

### 1

#### Description of health condition studied

Premature infant

#### ICD-10 code

P07

#### ICD-10 code description

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

## Primary outcomes

### 1

#### Description

The duration of deep sleep

#### Timepoint

After intervention

#### Method of measurement

Ales doctor tools

### 2

#### Description

Respiratory rate

#### Timepoint

Q 5 minute from 10 minutes before intervention until 10 minutes after intervention

#### Method of measurement

Observation

### 3

#### Description

Heart rate

#### Timepoint

Q 1 minute from 10 minutes before intervention until 10 minutes after intervention

#### Method of measurement

Monitor

### 4

#### Description

Oxygen saturation

#### Timepoint

Q 1 minute from 10 minutes before intervention until 10 minutes after intervention

#### Method of measurement

Monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group I: Control group: Infants receive no intervention in this group and they will be monitored in terms of dependent variables for 40 minutes. The headphone will be placed on the infants' ears for 40 minutes, but no sound will be played.

**Category**

Other

**2**

**Description**

Group II: Placebo: The recorded sound of another person's heartbeats will be played at 50 dB intensity for infants through headphones for 20 minutes.

**Category**

Other

**3**

**Description**

Group III: intervention: The recorded sound of mother's heartbeats will be played at 50 dB intensity for infants through headphones for 20 minutes.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Mashhad Imam Reza Hospital

**Full name of responsible person**

Zahra Yazdani

**Street address**

**City**

Mashhad

**2**

**Recruitment center**

**Name of recruitment center**

Mashhad Omolbanin Hospital

**Full name of responsible person**

Zahra Yazdani

**Street address**

**City**

Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor For Research, Mashhad University Of Medical Sciences

**Full name of responsible person**

Tayebeh Reyhani

**Street address**

Faculty of Nursing and Midwifery

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor For Research, Mashhad 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**

Mashhad University Of Medical Sciences

**Full name of responsible person**

Zahra Yazdani

**Position**

Master Student of Neonatal Intensive Care

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

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Dr Ahmad Shah Farhat

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Neonatologist

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## 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*