

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of live maternal voice on physiologic factors of premature infants hospitalized in NICU

#### Protocol summary

##### Summary

are categorized into 3 groups. First group: The infants of this group listen to their mothers' live voice for 10 minutes. Second group: In this group, the mother stands beside the incubator for 10 minutes but does not speak to the infant. Third Group: The infants of this group listen to the nurse's (researcher) live voice for 10 minutes. The study is in this way: The infants understudy are placed inside the incubator. For all of the three groups, 10 minutes before the intervention, the nurse records heart rate, blood oxygen saturation, blood pressure and respiratory rate every five minutes using a pulse oximeter made in USA (Masimo) which is on one side positioned on the infant's foot and on the other side attached to a monitoring system (Saadat) made in Iran through three chest leads and neonatal pressure cuffs in various sizes each of which are connected to the system with separate cables. Similarly, the vital signs are recorded in the second 10 minutes; but this time in three different situations including mother's presence with her voice, mother's presence without voice and nurse's presence with her voice. In the last 10 minutes also the vital signs are recorded without the mother or nurse's presence. It should be noted that the infants are not being fed during the intervention and evaluation and they are under study for 3 consecutive days from 3 to 5 PM. The mother and the nurse are not allowed to touch the infant during the intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015081623636N1**  
Registration date: **2015-09-16, 1394/06/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-16, 1394/06/25

##### Registrant information

###### Name

Mozhgan Ahmadi Vastani

###### Name of organization / entity

Babol University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 911 353 0723

###### Email address

m.ahmadi@mubabol.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Babol University of Medical Sciences

##### Expected recruitment start date

2014-12-21, 1393/09/30

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of live maternal voice on physiologic factors of premature infants hospitalized in NICU

##### Public title

The effect of live maternal voice on physiologic factors of premature infants

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion Criteria: Premature infants with gestational age of 28 to less than 37 weeks; Birth weight of more than 1 kilograms and less than 2.5 kilograms; Infants that are at least 3 days old; Infants that are kept in incubator, have physiological stability and no congenital anomalies and their inclusion in the study is confirmed by the shift attending; Infants that are not under the effect of any kind of ventilation such as nasal cannula, positive pressure ventilation through nasal mask or ventilator; Receiving no muscle relaxant drug; Not having surgery; Infants that are merely fed by their mother's milk.  
Exclusion Criteria: Startle reflex/ (ABR) hearing test indicate hearing impairment; Definitive diagnosis of the following issues during the intervention: Intraventricular hemorrhage with grade 2 and above; Necrotizing enterocolitis; patent ductus arteriosus; sepsis; acute lung disease; anemia (Hb<10gm / dr); occurrence of seizure and mother's unwillingness to cooperate; Infants that use pacifier or are fed by things other than mother's milk; Reports that indicate mother's known addiction to alcohol, addictive drugs (narcotic drugs) and psychotropic substances; The mother receive hypnotic drugs in the intervention day.

**Age**

From **3 days** old to **29 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Babol University of Medical Sciences,

**Street address**

Vice- Chancellor for Research Technology Affairs,  
Babol University of Medical Sciences, Ganjafroz  
Street, Babol, Mazandaran Province, IR Iran.

**City**

Babol

**Postal code**

4717647745

**Approval date**

2015-06-02, 1394/03/12

**Ethics committee reference number**

MUBABIL.REC.1394.36

**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**

Heart rate

**Timepoint**

10 minut before-10 minute during-10 minute after intervention

**Method of measurement**

Monitor

**2****Description**

Respiratory rate

**Timepoint**

10 minut before-10 minute during-10 minute after intervention

**Method of measurement**

Monitor

**3****Description**

Blood pressure

**Timepoint**

10 minut before-10 minute during-10 minute after intervention

**Method of measurement**

Monitor

**4****Description**

Saturation of pressure of O2

**Timepoint**

10 minut before-10 minute during-10 minute after intervention

**Method of measurement**

Monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First group: The infants of this group listen to their mothers' live voice for 10 minutes. This group, 10 minutes before, 10 minutes during, 10 minutes after the intervention, the nurse records heart rate, blood oxygen saturation, blood pressure and respiratory rate every five minutes.

#### Category

Behavior

### 2

#### Description

Second group: In this group, the mother stands beside the incubator for 10 minutes but does not speak to the infant. This group, 10 minutes before, 10 minutes during, 10 minutes after the intervention, the nurse records heart rate, blood oxygen saturation, blood pressure and respiratory rate every five minutes.

#### Category

Behavior

### 3

#### Description

Third Group: The infants of this group listen to the nurse's (researcher) live voice for 10 minutes. This group, 10 minutes before, 10 minutes during, 10 minutes after the intervention, the nurse records heart rate, blood oxygen saturation, blood pressure and respiratory rate every five minutes.

#### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Boali Hospital

##### Full name of responsible person

Mozhgan Ahmadi Vastani

##### Street address

Boali Hospital, Pasdaran boulevard, Sari, Mazandaran Province, IR Iran

##### City

Sari

### 2

#### Recruitment center

##### Name of recruitment center

Emam Hospital

##### Full name of responsible person

Mozhgan Ahmadi Vastani

##### Street address

Emam Hospital, Amir mazandarani boulevard, Sari, Mazandaran Province, IR Iran

##### City

Sari

### 3

#### Recruitment center

##### Name of recruitment center

Amirkola Children's Hospital

##### Full name of responsible person

Mozhgan Ahmadi Vastani

##### Street address

Amirkola Children's Hospital, Amirkola, Babol, Mazandaran Province, IR Iran.

##### City

Amirkola

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Chancellor for Research Technology Affairs

##### Street address

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran.

##### City

Babol

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

##### Full name of responsible person

Mozhgan Ahmadi Vastani

##### Position

Student of Ms In Neonatal Intensive care Unit

**Other areas of specialty/work**

**Street address**

Babol University of Medical Sciences, Ganjafroz  
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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Yadolla Zahed Pasha

**Position**

Neonatologist, Professor

**Other areas of specialty/work**

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Babol University of Medical Sciences

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Mozhgan Ahmadi Vastani

**Position**

Student of Ms In Neonatal Intensive care Unit

**Other areas of specialty/work**

**Street address**

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Street, Babol, Mazandaran Province, IR Iran.

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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*