

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
Street, Babol, Mazandaran Province, IR Iran.

City

Babol

Postal code

4717647745

Phone

+98 11 3310 5346

Fax

+98 11 3219 0181

Email

Mozhganahmadivastani@gmail.com

Web page address

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

Street address

Babol University of Medical Sciences, Ganjafroz
Street, Babol, Mazandaran Province, IR Iran.

City

Babol

Postal code

4717647745

Phone

+98 113219959296

Fax

+98 981132190181

Email

Zypasha@gmail.com

Web page address

Person responsible for updating data

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
Street, Babol, Mazandaran Province, IR Iran.

City

Babol

Postal code

4717647745

Phone

+98 11 3310 5346

Fax

00891132190181

Email

Mozhganahmadivastani@gmail.com

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