

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Assessing of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU

#### Protocol summary

##### Summary

The purpose of this study was to Assess of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU. Inclusion criteria: Infants hospitalized in neonatal intensive care units in selected hospitals in Tehran; when measuring pain or at least 3 hours before it, Sedatives have not received; The lack of Underlying disease and extensive surgery (e.g., abdominal surgery, etc.) that is causing pain; The lack of crippling diseases and anatomical defects members (hands and feet); No hearing impaired; At least 36 weeks gestational age; Requiring Blood samples is. Exclusion criteria: During the study, the infant is in trouble, as it is connected to the ventilator; when sampling is not done once the needles into the skin; when sedatives or tranquilizers should be used for infants during Blood samples. The population included all infants admitted to the intensive care unit of a hospital, sampling is simple random sampling. There are 60 samples and is performed by both sexes. From 10 minutes before to 10 minutes after taking blood samples mother's voice is played And physiological responses before, during and 10 minutes after blood samples are document and pain at the time of entry and one minute after needle insertion is measured Using NIPS scale, Then effects on physiological responses to pain compared with a control group of infants who are not playing mother's voice.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014011416225N1**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-03, 1393/05/12

##### Registrant information

###### Name

Elham Azarmnejad

###### Name of organization / entity

Baghiatollah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

00982122286057-22289941

###### Email address

azarm.elham@yahoo.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Baghiatollah University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2014-08-26, 1393/06/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessing of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU

##### Public title

Familiar auditory stimuli on physiological responses induced by painful stimulation in infants

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria: Infants hospitalized in neonatal intensive care units in selected hospitals in Tehran; when measuring pain or at least 3 hours before it, Sedatives have not received; The lack of Underlying disease and extensive surgery (e.g., abdominal surgery, etc.) that is causing pain; The lack of crippling diseases and anatomical defects members (hands and feet); No hearing impaired; Must have at least 36 weeks gestational age; Requiring Blood samples is. Exclusion criteria: During the study, the infant is in trouble, as it is connected to the ventilator; when sampling is not done once the needles into the skin; when sedatives or tranquilizers should be used for infants during Blood samples

### **Age**

To **1 year** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Not randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Baghiatollah University of Medical Sciences

##### **Street address**

Mollasadra street

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2014-05-25, 1393/03/04

#### **Ethics committee reference number**

5291/3/340/س

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Understand the relationship between auditory stimulation on physiological responses induced by painful stimulation in infants hospitalized in intensive care

#### **ICD-10 code**

General sy

#### **ICD-10 code description**

Acute pain R52.0

## **Primary outcomes**

### **1**

#### **Description**

Physiological responses

#### **Timepoint**

Before the intervention, during intervention, post-intervention

#### **Method of measurement**

Using a pulse oximeter Mobile

## **Secondary outcomes**

### **1**

#### **Description**

Pain

#### **Timepoint**

Before the intervention, during intervention, post-intervention

#### **Method of measurement**

NIPS pain scale

## **Intervention groups**

### **1**

#### **Description**

In the test group, the mother's voice is played for 10 minutes before and 10 minutes after blood sampling continues. Mother's voice can be recorded using a software program, Cool Edit2000, and with two small speakers on either side of the Infant's head at a distance of 20 cm from the Infant's ear, placed in the incubator. The Voice being broadcast in about 50 to 60 dB is set.

#### **Category**

Other

### **2**

#### **Description**

In the control group, no interventions are not just physiological variables (heart rate, respiratory rate, blood pressure, oxygen saturation, and pain) are measured.

#### **Category**

N/A

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Baghiatollah Hospital

**Full name of responsible person**

Forough Sarhangy

**Street address**

Mollasadra street

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Baghiatollah University of Medical Sciences

**Full name of responsible person**

Dr. Rokhsari

**Street address**

Alley Borna-Sheikh Bahai Avenue South

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Baghiatollah 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**

Baghiatollah University of Medical Sciences

**Full name of responsible person**

Elham Azarmnejad

**Position**

Master student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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MS

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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*