

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparing the effect of listening to music therapy and swaddling on neonate's physiological and pain intensity changes during blood sampling in the neonatal intensive care unit

#### Protocol summary

##### Summary

The aim of this study was to compare the effect of music therapy and Swaddling on pain is caused by venous blood sampling in premature babies. This clinical trial on 51 premature an infant hospitalized in neonatal intensive care medical center will Bushehr Persian Gulf. Inclusion criteria included: Written take informed consent from parents, Gestational age less than 37 weeks, After at least 24 hours of birth, Exclusion criteria: Congenital abnormalities, Chromosomal or neurologic, Babies who have Undergone surgery, Babies who are connected to ventilator. Infants randomly were divided into three groups of 17 subjects in each block ; Music group a, The Swaddling group b and group c was considered as control; From 5 minutes before blood sampling, Blood samples collected during and 5 minutes after music player in group a and group b 5 minutes before and 5 minutes after blood sampling, The Baby wrapped in a thin sheet. In all three groups the heart rate and arterial oxygen saturation before, During and after the blood sample is measured and will be recorded. The baby's face in close-up shooting can be seen, a film made by a research assistant unaware of the type of intervention , Then questionnaire of premature infant pain profile is completed by a research assistant. To measure physiological parameters, a pulse oximetry is connected to baby is used.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017040433209N1**  
Registration date: **2017-05-28, 1396/03/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-28, 1396/03/07

##### Registrant information

###### Name

Aliakbar karimi

###### Name of organization / entity

Bushehr University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 4333 3559

###### Email address

a.karimi@bpums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research Bushehr University of Medical Sciences

##### Expected recruitment start date

2017-05-22, 1396/03/01

##### Expected recruitment end date

2017-07-21, 1396/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of listening to music therapy and swaddling on neonate's physiological and pain intensity changes during blood sampling in the neonatal intensive care unit

##### Public title

The effect of music therapy and swaddling on neonatal pain when taking blood.

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: Written take informed consent from parents; Gestational age less than 37 weeks; After at least 24 hours of birth; After maximum of one month of birth; Apgar score above 6 in the first 5 minutes; Awake and calm baby; Do not feed the baby 30 minutes before the intervention; Do not receive any medication or substance of analgesics and sedatives during the 6 hours before the intervention; The absence of rash (dry skin, red spots, hemangiomas) in infants; In addition, Collected blood samples in the same day was the first time an infant sampling and sampling has not been done before  
Exclusion criteria: Congenital abnormalities; Chromosomal or neurologic; Intraventricular hemorrhage, Seizures, Epilepsy; Babies who have Undergone surgery, Babies who are connected to ventilator

**Age**

From **1 day** old to **1 month** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **51**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Bushehr University of Medical Sciences

**Street address**

No. 12, Bahmani, Yasini Avenue, Bushehr University of Medical Sciences Campus, Iran, Bushehr

**City**

Bushehr

**Postal code**

7514633341

**Approval date**

2017-03-12, 1395/12/22

**Ethics committee reference number**

ir.bpums.rec.1395.165

**Health conditions studied****1****Description of health condition studied**

pain

**ICD-10 code**

R52.0

**ICD-10 code description**

Acute pain

**Primary outcomes****1****Description**

Pain

**Timepoint**

5 Minutes before blood sampling, Blood sampling during and 5 minutes after the blood sampling

**Method of measurement**

Premature infant pain profile questionnaire

**2****Description**

Behavior

**Timepoint**

5 Minutes before blood sampling, Blood sampling during and 5 minutes after the blood sampling

**Method of measurement**

Premature infant pain profile questionnaire

**Secondary outcomes****1****Description**

Heart rate

**Timepoint**

5 Minutes before blood sampling, Blood sampling during and 5 minutes after the blood sampling

**Method of measurement**

Pulse oximetry and Premature infant pain profile questionnaire

**2****Description**

Arterial blood oxygen saturation

**Timepoint**

5 Minutes before blood sampling, Blood sampling during and 5 minutes after the blood sampling

**Method of measurement**

Pulse oximetry and Premature infant pain profile questionnaire

## Intervention groups

1

### Description

Baby diapers clean without clothes and only one heating device placed under then 5 minutes before blood sampling, Blood sampling during and 5 minutes after the blood sample the music is played.

### Category

Prevention

2

### Description

Infant without clothes and only with a clean diaper, By the researcher in a thin linen wrapped in swaddling clothes.

### Category

Prevention

3

### Description

The control group, Infants in this group receive all routine care during hospitalization.

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Central Bushehr Persian Gulf Martyrs

#### Full name of responsible person

Doctor Alireza Hajyvny

#### Street address

#### City

Bushehr

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research,bushehr University of Medical Sciences

#### Full name of responsible person

Afshin ostovar doctor

#### Street address

NO 12, Campus of Medical Sciences,Bahamni, Yasini Avenue, Bushehr Bushehr

#### City

bushehr

#### 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,bushehr 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

Bushehr University of Medical Sciences

#### Full name of responsible person

sharafat Akabarian

#### Position

Master / faculty

#### Other areas of specialty/work

#### Street address

NO 7, School of Nursing and Midwifery,Bahmani, Yasini st, Bushehr

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#### Phone

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Sh.akabarian@bpums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

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## **Person responsible for updating data**

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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*