

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

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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 Akaberian

Position

Master / faculty

Other areas of specialty/work

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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