

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Music and oral sucrose on Pain During blood sampling in Preterm Infants ,in Neonatal Intensive Care Unite of Shahid Akbarabadi treatment & education center

Protocol summary

Summary

Objectives: : During hospitalization in the neonatal intensive care unit, preterm infants are vulnerable against a wide range of stress and stimulation, therefore they need the effective pain management during and after the painful and frequent painful interventions. Design: 4 groups, double blind randomized control trial. Setting and conduct: Neonatal Intensive Care Unit (NICU) of Shahid Akbar Abadi educational & treatment center. Participants: 120 healthy preterm infants with gestational age 32-36 weeks; Birth weight over 1500 gr; Apgar score at 1 and 5 min after birth ≥ 7 ; postnatal age 48 hours or more; Oral feeding, Receiving no sedative drugs during the last 48 hours, will randomly assigned to three experimental groups and control group. Observation of any abnormal physiologic responses; touch and medical or nursing interventions during study; also blood sampling for more than one location; and except of radial and brachial areas, infant will be excluded. Intervention: Two min before blood sampling, in the sucrose group 0.5 ml oral sucrose solution 24% will be administered with a syringe on the anterior portion of the tongue, also, braham`s lullaby will be played for 10 minutes at 40-50 db via earphone in the music group. In the combination group, simultaneously 0.5 ml sucrose 24% will be administered and lullaby music will be played for infants. Physiologic responses and facial changes will be recorded simultaneously with using two video cameras during different phases. For blinding, in control group, 0.5 ml sterile water will be administered with a syringe on the anterior portion of the tongue, the earphone will be used for all groups , meanwhile a research assistant will analyze the films. Main outcome: Pain score will be calculated before blood sampling (base line), 30 seconds after the start of the blood sampling, 30 seconds and 10th min post blood sampling by using the Premature Infant Pain Profile

(PIPP).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101052324N7**

Registration date: **2012-04-30, 1391/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-30, 1391/02/11

Registrant information

Name

Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-04-08, 1391/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Music and oral sucrose on Pain During blood sampling in Preterm Infants ,in Neonatal Intensive Care Unite of Shahid Akbarabadi treatment & education center

Public title
Effect of Music and/ or oral sucrose on Pain During blood sampling in Preterm Infants

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Gestational age between 32-36 weeks; Birth weight 1500 grams or more; Apgar score at 1 and 5 min after birth, ≤ 7 ; Healthy infant (no evidence of congenital anomaly and other diseases); Confirmation of hearing by using ABR device; Have no hyper-responsiveness to the sound in the nursery reports; Non addicted mothers; Postnatal age 48 hours or more; Oral feeding, Receiving no sedative drugs during the last 48 hours. Exclusion criteria: Un willingness the parents for complete the study; Abnormal physiologic responses such as heart rate above 200 beat per min or lower than 100 beat per min, deceleration of oxygen saturation level under 80% during intervention; Any problem to record of physiological and behavioral responses and Observation of any abnormal physiologic responses; touch and medical or nursing interventions during study; Duration of blood sampling more than 4 minutes; Blood sampling is performed in more than one location; ; Blood sampling is performed except radial and brachial areas.

Age
To **1 year** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
no

Secondary trial Id

no

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical commitment of Tehtan University of Medical Sciences

Street address

Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran

City

Tehran

Postal code

Approval date

2011-11-09, 1390/08/18

Ethics committee reference number

1434

Health conditions studied

1

Description of health condition studied

Pain in preterm newborns

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Pain score in preterm newborns

Timepoint

Before, during and after venipuncture

Method of measurement

by PIPP (Premature Infant Pain Profile)

Secondary outcomes

empty

Intervention groups

1

Description

1-administration of 0.5 ml oral sucrose solution 24% with a syringe on the anterior portion of the tongue, 2-playing lullaby music for 10 minutes at 40-50 db via earphone 3- lullaby music for 10 minutes at 40-50 db via earphone accompany with 0.5 ml oral sucrose solution 24%

Category

2**Description**

0.5 ml sterile water will be given to control group

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Akbar abadi educational & treatment center

Full name of responsible person

Maryam Keshavarz

Street addressShahid Akbar abadi educational & treatment center ,
Molavi St. Tehran**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**vice chancellor for research (Research and
technology)- Tehran University of Medical Sciences**Full name of responsible person**Dr. Akbar Fotohi- vice chancellor for research of
Tehran University of Medical Sciences**Street address**Sixth floor ,Central office, Ghods St, Keshavarz Blvd-
Tehran, Iran**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourcevice chancellor for research (Research and technology)-
Tehran 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**School of Nursing Midwifery, Tehran University of
Medical Sciences**Full name of responsible person**

Maryam Keshavarz

Position

Assistant Professor in Midwifery education

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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