Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 age32-36 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

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Scienses

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

Prevention

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 address
Shahid 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
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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 source
vice 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
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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