Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of music therapy on pain responses of blood sampling in premature infant

Protocol summary

Summary

The aim of this study is to determine the effect of music therapy on pain responses of premature infants during and following blood sampling. This is an experimental study with cross- over design which was conducted on 20 premature infants hospitalized in intensive care unit of a hospital affiliated to Tehran University of Medical Sciences. Infants were randomly studied once as experiment and once as control, so each infant was considered as its own control to eliminate the influence of individual characteristics. Researcher assessed the pain responses caused by blood sampling in preterm infants. Physiological and behavioral responses of pain were assessed. We assessed heart rate and oxygen saturation level as physiological responses and we assessed sleep wake state and facial expressions (which was measured by neonatal facial coding system) as behavioral responses. In the intervention group transitions music was used from 5 minutes before blood sampling and continued until 10 minutes after blood sampling. At any time (experience or control) recording with two cameras was done from 10 minutes before sampling, during blood sampling and 10 minutes after sampling. One camera recorded facial expressions and body movements and at the same time another camera recorded the monitor of the infant. Then the films were reviewed by computer and physiological and behavioral changes were detected.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905034372N2**
Registration date: **2011-12-08, 1390/09/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-08, 1390/09/17

Registrant information

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Roghieh Karimi
Name of organization / entity
Nursing School of Tehran University of Medical Scienses
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of music therapy on pain responses of blood sampling in premature infant

Public title

Effect of music therapy on pain responses of blood sampling in premature infant

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: premature infants whose weights are less than 2500 grams, gestational age 29- 36 weeks, no congenital diseases, no intracranial hemorrhage or neurological disorders, level 1 or 2 of neonatal intensive care, not receiving any sedative in 24 hours before sampling, arterial sampling should be necessary for the infant, the site of sampling should not be the same in two times of sampling Exclusion criteria: no willingness to continue, becoming unstable during sampling, first time failure for trial to sampling
Age
To **1 year** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Review Committee of Tehran University of Medical Sciences
Street address
Floor 6, Central Building of Tehran University ,Intersection of Ghods & Keshavarz Blv
City
tehran
Postal code
Approval date
2010-08-07, 1389/05/16
Ethics committee reference number
623/130/89/ص

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 responses to blood sampling in premature infant
Timepoint
10 minutes before sampling to 10 minutes after sampling
Method of measurement
recording physiologic and behavioral signs of pain each 15 second by watching films recorded from monitor and face of infant

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Music therapy, starting from 5 minutes before sampling to 10 minutes after sampling
Category
Behavior

2

Description
Control group: no intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-asr hospital
Full name of responsible person
Fidan Shabani
Street address
Nosrat street, East side of Tohid sq.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Tehran University of Medical Sciences and Health Services

Full name of responsible person
Dr. Yunesiyan
Street address
floor 6, central bulding of university , Ghods, Keshavarz Blv.
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, Tehran University of Medical Sciences and Health Services
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
Nursing School of Tehran University of Medical Sciences and Health Services
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Person responsible for updating data

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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