Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of music on pain of heellance blood sampling in neonates

Protocol summary

Summary

The goal of this research is investigating the music's effects on the pain of heel blood sampling on infants of a hospital in Saveh city. The study's population is the infants who refer to 17-shahrivar hospital of Saveh city to perform thyroid screening test. Some inclusion criteria are as follows:,Gestational age is 37 to 42 weeks, Birth weight is 2500-4000 gr, The infants have not been received Naloxone during the last 24 hours. The infants have not been received sedative, tranquilizers or anticonvulsants within 12 hours before blood sampling and The infants are awake, quiet and without crying. Some exclusion criteria are as follows: If blood tests for thyroid disorder confirms hearing loss in infants and If the related tests diagnoses thyroid disorders. Infants will be selected by convenient sampling. Samples are randomly divided into three groups: Intervention group (1) tested by heart sound (60 persons), intervention group (2) tested by the song Lullaby (60 persons) and control group (60 persons). The mentioned procedure continues until the sample is completed. The researchers use headphones and MP3 player to prevent from bias in all three groups. First, for each infant is completed a questionnaire of demographic' information. Next, for intervention group (1) and (2) the music is played using a MP3 player and headphones from one minute before and during heel blood sampling, while for control group will not be played any music. The pain intensity is evaluated by researcher for each of the three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201098651N1**
Registration date: **2012-09-26, 1391/07/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-26, 1391/07/05

Registrant information

Name
Nasrin Safari
Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences approved research project

Expected recruitment start date

2011-10-22, 1390/07/30

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of music on pain of heellance blood sampling in neonates

Public title

Effect of music on pain in infants

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria:Gestational age is 37 to 42 weeks؛Birth weight is 2500-4000 gr؛The infants have not

been received Naloxone during the last 24 hours؛The infants have not been received sedative, tranquilizers or anticonvulsants within 12 hours before blood sampling؛ The infants have not been had any problem such as heart, respiratory, nervous or chromosomal abnormalities؛ The infants are awake, quiet and without crying؛ The age of infants' mothers is between 18 and 35 years. The exclusion criteria:If blood tests for thyroid disorder confirms hearing loss in infants؛If the related tests diagnoses thyroid disorders.

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

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
Arak University of Medical Sciences

Street address
School of Medical Sciences Saveh, Yas Avenue, Kaveh Industrial City, Saveh,Iran

City
Saveh

Postal code

Approval date
2011-09-05, 1390/06/14

Ethics committee reference number
8-112-90

Health conditions studied

1

Description of health condition studied
Heel pain during blood sampling

ICD-10 code
M79.6

ICD-10 code description
Pain in limb

Primary outcomes

1

Description
naonats pain

Timepoint
during intervention

Method of measurement
Using standard tools of infant pain assessment tools (DAN) (Douleur Aiguë Nouveau-né

Secondary outcomes

empty

Intervention groups

1

Description
Control group: no music, do not receive

Category
Other

2

Description
Intervention group I:For this group, one minute before blood sampling and the whole time of the blood sampling, heart beat sound is played with headphones

Category
Other

3

Description
Intervention group II:For this group, one minute before blood sampling and the whole time of the blood sampling lullaby music is played with headphones

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
17 Shahrivar Hospital

Full name of responsible person
Nasrin Safari

Street address
School of Medical Sciences Saveh, Yas Avenue, Kaveh Industrial City, Saveh,Iran

City
Saveh

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
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School of Medical Sciences Saveh, Yas Avenue, Kaveh Industrial City, Saveh,Iran
City
Saveh
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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