Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of whistling compared with Buzzy device during blood sampling on pain and fear in children’s emergency department

Protocol summary

Study aim
Comparison of the effect of whistling and using vibrating bees during blood sampling on pain and fear of children in the emergency department

Design
A musical doll in the shape of a bee with an approximate size of 15 cm with the ability to create vibration at the rate of 95-90 Hz was made, which is a portable cold bag with a linen cover in the form of a bracelet attached to it. When the child is with the parents, the nurse performing the blood sampling procedure, this musical bee doll, with the bag attached to it, is closed for 5 minutes, at a distance of about 5-10 cm above the blood sampling site, and in one minute The vibration end will be applied, then the child will enter the blood collection room with one of the parents and blood collection will be done immediately. In the second group, a bee-shaped balloon whistle with a long straw at the end will be given to the child and the child will be taught to die inside the straw 5 minutes before entering the room and whistle. Fill the air and the toy will be in the child's hand until the end of the blood collection and will continue to whistle during the blood collection process. Finally, the whistle will be given as a gift to the intervention group. The third group of the control group routine blood sampling.

Settings and conduct
The pediatric emergency department Najaf health centers

Participants/Inclusion and exclusion criteria
Participants are children who need to be sampled during hospitalization, and if they are placed in two experimental groups, the fear and pain caused by the blood sampling process will probably be reduced.

Intervention groups
In the first intervention group, vibrating bees with a cold pack is used. The second group is the use of whistling during blood sampling. The third control group that blood sampling will be done with a routine program

Main outcome variables
Pain and fear caused by blood sampling

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211211053351N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
sadeghi tahereh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-28, 1400/10/07

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of whistling compared with Buzzy device during blood sampling on pain and fear in children’s emergency department

Public title
Effects of whistling compared with Buzzy device during blood sampling on pain and fear in children’s

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The child needs blood sampling. At least one parent is present during blood sampling. Be the first child injection experience at this reception. The injection site of the inner crease of the elbow or forearm should be selected and there should be no scar or skin problem. The child does not have sensory-neurological, vascular, hematological, verbal and cognitive disorders and chronic diseases. • The child is awake before the intervention and has not received sedatives, sedatives or narcotics. Before the intervention, the child's pain level should be below three with the Wong-Baker FACES tool. The child and parents have informed consent to participate in the intervention.

Exclusion criteria:
Dissatisfaction of parents and children with research
Failure to draw blood for the first time

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The method used to generate a random allocation sequence is blocked. Block randomization ensures that there are no groups between the groups at any time interval during the randomization of a significant imbalance, and at each point the number of participants in each group is equal. Sampling in this research will be that sampling initially will be conducted in a "non-random" way for the purpose of children entering the research and assigning them to 3 groups (group: vibrating bee / whistling / control) will be random; In this way, the assignment of samples to intervention groups (vibrating bee / whistling / control) will be done by random assignment (lottery by blocking). In this intervention, we have three groups; first by assigning the code to the groups, the groups will be determined(Group A: vibration bee B: whistling C: control). 6 blocks with 3 pieces Characterized [(ABC(1)- ACB (2)-CAB (3)-BCA (4)-CBA (5)- BAC(6)]. Then, random numbers are selected between one to six (eg, 1, 4, 5, ...), and finally the list of treatment allocations based on random numbers will be determined.

Blinding (investigator's opinion)
Not 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 Mashhad University of Medical Sciences

Street address
IbnSina 2St., School of Nursing and Midwifery, Khorasan Razavi, Mashhad, Iran

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Approval date
2021-07-27, 1400/05/05

Ethics committee reference number
IR.MUMS.NURSE.REC.1400.039

Health conditions studied

1

Description of health condition studied
Fear and pain caused by blood sampling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain caused by blood sampling

Timepoint
Before, during and after blood sampling

Method of measurement
Children's pain will be assessed using the Wong Baker Smile Scale.

2

Description
Fear caused by blood sampling

Timepoint
Before, during and after blood sampling
Method of measurement
Fear of blood sampling will be measured by the CMFS Children's Fear Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use vibrating bees with cold packs In this study, a musical doll in the shape of a bee with an approximate size of 15 cm with the ability to create vibration at the rate of 95-90 Hz was made, which is a portable cold bag with a linen cover in the form of a bracelet attached to it. When the child is with the parents, the nurse performing the blood sampling procedure, this musical bee doll, with the bag attached to it, is closed for 5 minutes, at a distance of about 5-10 cm above the blood sampling site, and in one minute The vibration end will be applied, then the child will enter the blood collection room with one of the parents and blood collection will be done immediately.
Category
Treatment - Other

2

Description
Intervention group: Use a bee-shaped whistle when drawing blood، before entering the blood collection room, a bee-shaped balloon whistle with a long straw at the end will be given to the child and the child will be taught to die inside the straw 5 minutes before entering the room and whistle. Fill the air and the toy will be in the child's hand until the end of the blood collection and will continue to whistle during the blood collection process. Finally, the whistle will be given as a gift to the intervention group.
Category
Treatment - Other

3

Description
The third group of the control group will enter the blood collection room with one of their parents according to the routine blood sampling process in the emergency department of the child and sampling will be done.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Najaf Al Zahra
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice Chancellor of Mashhad University of Medical Science
Full name of responsible person
Dr Majed Ghayour
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Third floor, Vice Chancellor for Research and Technology, University of Medical Sciences, next to Hoveyzeh Cinema, Daneshgah St., Mashhad, Khorasan Razavi, Iran
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Grant name
4000366
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor of Mashhad University of Medical Science
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic

Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable