Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of vibration bee with heat and cold on the pain caused by intravenous cannula insertion in children 3 to 6 years

Protocol summary

Study aim

Comparison of the effect of vibration bee with heat or cold on the pain of Intravenous catheter insertion in 3-6 years old children

Design

A randomized controlled clinical trial (3 groups) with parallel group, double-blind (evaluator and statistical).

Settings and conduct

location: Emergency Department and Clinic of Mashhad Pediatric Hospital. Patients will be included in the study with inclusion criteria and will be excluded if excluded. First, the purpose of the study is explained to children (who are eligible for inclusion) and their parents. After obtaining verbal consent from the child and written consent from the parents, the children will be included in the study. The intervention will be performed by the nurse injecting the intravenous catheter and the assessor will be blind. Questionnaires will be written in group code and the assessor will be blinded.

Participants/Inclusion and exclusion criteria

Child 3 to 6 years old with elective problem The first experience of injection for child in this admission. The child has no sensory-neurological, vascular, hematologic, verbal and cognitive impairment and chronic illness Before intervention, the child is alert and has not received sleepy, sedative and narcotic drugs.

Intervention groups

First Intervention group : Heat vibrating bee group: The vibrate bee puppet, which is attached to a warm bag with a local heat of 39-40 ° C below, will be closed for 5 minutes at the location mentioned and in the last minute the vibration will apply. Second Intervention group : At the same condition; But the cold bag is used at zero degrees instead of the local heat. Control group ; Group of vibrating bees at room temperature

Main outcome variables

Reduce the pain of intravenous catheter insertion for children

General information

Reason for update

Acronym

زنبوک وبیره

IRCT registration information

IRCT registration number: **IRCT20181104041553N1**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-31, 1398/06/09

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of vibration bee with heat and cold on the pain caused by intravenous cannula insertion in children 3 to 6 years

Public title
Comparison of the effect of vibration bee with heat and cold and room temperature on the pain caused by intravenous cannula insertion in children

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Child 3 to 6 years old with elective surgery Before entering the section or operating room, child need to Intravenous Catheter insertion At least one of the parents is present during Intravenous Catheter insertion The first experience of injection for child in this admission. The injection site is internal flexure of elbow or forearm and should not have a scar or skin problem The child has no sensory-neurological, vascular, hematologic, verbal and cognitive impairment and chronic illness Before intervention, the child is alert and has not received sleepy, sedative and narcotic drugs Before the intervention, the child's pain level is 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 the child from the research Not successful first injection If the catheter insertion to the vein after it enter into the hand of child, it will take more than 20 seconds.

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

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

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 (groups: vibration bee with heat/ vibration bee with cold/ vibration bee with room temperature) will be random; In this way, the assignment of samples to intervention groups (vibration bee with heat and vibration bee with cold) or control group(vibration bee with room temperature) 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 with heat and Group B: vibration bee with cold and Group C: vibration bee with room temperature). 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. By drawing a lot, it will be clear what the sequence of doing the job is.

Blinding (investigator's opinion)
Double blinded

Blinding description
The nurse who do this procedure(Intravenous Catheter Insertion) draws and either cools or warms the pack itself (in the intervention group) or at room temperature (in the control group):Therefore, the researcher will be blind when scoring on the relevant tool (for evaluation of the outcome) . Only the code for each child's tool will be written: so the statistical evaluator will be blind.

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
Mashhad School of Nursing and Midwifery, Ibn Sina Street, Doctoral intersection, University Avenue

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2019-06-13, 1398/03/23

Ethics committee reference number
شماره IR.MUMS.NURSE.REC.1398.019

Health conditions studied

1

Description of health condition studied
the pain induced with Peripheral venous catheter

ICD-10 code

ICD-10 code description

R52.0

Primary outcomes

1

Description
Pain caused by Peripheral Vein Catheter Insertion
Timepoint
Before and Immediately after Peripheral Vein Catheter Insertion
Method of measurement
Wong-Baker FACES

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group : Heat vibrating bee group: The vibrate bee puppet, which is attached to a warm bag with a local heat of 39-40 ° C below, will be closed for 5 minutes at the location mentioned and in the last minute the vibration will apply.
Category
Treatment - Devices

2

Description
Second Intervention group : Cool vibrating bee group: The vibrate bee puppet, which is attached to a cool bag with a local cold of 0 ° C below, will be closed for 5 minutes at the location mentioned and in the last minute the vibration will apply.
Category
Treatment - Devices

3

Description
Control group: vibrating bee group with room temperature : The vibrate bee puppet, will be closed for 5 minutes at the location mentioned and in the last minute the vibration will apply.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Children 's Hospital Akbar Mashhad
Full name of responsible person
Sadeghi tahere
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Vice chancellor for research and technology, Mashhad University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
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
maryam sahebkar moeini

Position
nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Nursery

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Person responsible for updating data

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Position
nurse

Latest degree
Bachelor

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available