

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 ویبره

##### 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

##### Name

Maryam Sahebkar Moeini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3881 7980

##### Email address

sahebkar961@mums.ac.ir

##### 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

##### Street address

Fakouri Boulevard, Shahid Kaveh Boulevard, opposite Kaveh 14

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9177899191

#### Phone

+98 51 3871 3801

#### Fax

+98 51 3870 9201

#### Email

p.relationships@mums.ac.ir

## 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

##### Street address

Vice chancellor for research and technology, Mashhad University of Medical Sciences, University Street, opposite University Street 18

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3841 2081

##### Email

Ramresearch@mums.ac.ir

#### 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

**Street address**

plaque 559, between 39 and 41 Yousefzadeh Avenue,  
Khwaja Rabi Street

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9149685674

**Phone**

+98 51 3742 0198

**Email**

sahebkar mm961@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

tahereh sadeghi

**Position**

Assistant Professor of Nursing

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, University Ave,  
Doctoral Crossroad, Ibn Sina St.

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Fax**

+98 51 3859 7313

**Email**

sadeghit@mums.ac.ir

## Person responsible for updating data

**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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plaque 559, between 39 and 41 Yousefzadeh Avenue,  
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**Postal code**

9149685674

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**Email**

sahebkar mm961@mums.ac.ir

## 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