Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety in children

Protocol summary

Study aim
The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety in children

Design
In this study, samples will be randomly divided into three groups using online software(https://www.randomizer.org/). A quasi-experimental clinical trial study with a control, single-blind and randomized design.

Settings and conduct
The study will be conducted in one of the selected clinics under the supervision of Qom University of Medical Sciences. In this study, all 6-year-old children referred for vaccination will be randomly assigned to one of three control, intervention and placebo groups. In this study, the researcher will be unaware of the type of intervention in the placebo and intervention groups.

Participants/Inclusion and exclusion criteria
inclusion 1. The child should be conscious and not have any identified problem in mental, hearing, sight, and verbal abilities. 2. No presence of scar, wound or damage in the point the device is put. 3. No usage of painkillers or anxiety-reducing medications in the past 8 hours. 4. No presence of cold sensitive diseases like Reynolds and local neural anesthesia. exclusion: No toleration the device by the child during the procedure

Intervention groups
1. in control group, vaccination procedure will be as the clinic's normal routine. 2. in intervention group, vaccination procedure will be as the clinic's normal routine with ice bag and switch on device. 3. in placebo group, vaccination procedure will be as the clinic's normal routine with switch off device.

Main outcome variables
1. The score of pain in Wong-Baker Faces Pain Rating Scale 2. The score of anxiety in The Children Emotional Manifestation Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190603043812N1**
Registration date: **2019-09-08, 1398/06/17**
Registration timing: **prospective**

Last update: **2019-09-08, 1398/06/17**
Update count: **0**

Registration date
2019-09-08, 1398/06/17

Registrant information

Name
Maryam khoshqadam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3291 3346

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-13, 1398/06/22

Expected recruitment end date
2019-09-21, 1398/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety in children

Public title

The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety in children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The child should be conscious and not have any identified problem in mental, hearing, sight, and verbal abilities. No presence of scar, wound or damage in the point the device is put No usage of painkillers or anxiety-reducing medications in the past 8 hours No presence of cold sensitive diseases like Reynolds and local neural anesthesia. 6-year-old children who were clients of selected clinic which is under supervision of Qom University of Medical Sciences for vaccination and were qualified and eager to take part in the research.

Exclusion criteria:

No toleration the device by the child during the procedure

Age

From **6 years** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, samples are put in three groups randomly by the online application (https://www.randomizer.org/). 105 closed envelopes are offered to each child. There is a number between 1 and 105 in each envelope. Children are put in one of the three groups based on the numbers they chose.

Blinding (investigator's opinion)

Single blinded

Blinding description

Researcher is not informed about type of intervention and placebo group in this way: the vaccinator is told to inform the researcher to enter the room and fill in the survey if the child is in control group; if the child is in placebo or intervention group, the device (buzzy) is put on the child’s arm, then the researcher is asked to enter the room but does not know if the device is switched on or off.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC.1397.248

Health conditions studied

1

Description of health condition studied

The effect of combined stimulation of external cold and vibration during immunization on pain and anxiety in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The score of pain in Wong-Baker Faces Pain Rating Scale

Timepoint

After vaccination, the child is asked to choose the smiley which corresponds to the severity of the pain they experienced. Supervising nurse also chooses the smiley corresponding to severity of child’s pain with a certain tool.

Method of measurement

Questioner

2

Description

The score of anxiety in The Children Emotional Manifestation Scale

Timepoint

This scale is completed in two steps by the supervising nurse (researcher). After choosing the group randomly and before entering the vaccination room, child’s anxiety is measured and recorded based on their emotional demonstration scale. Then the anxiety is measured and recorded immediately after disinfecting the injection

point and during injection of the vaccine.

Method of measurement

Questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1.Preparing Buzzy device, ice bag, and other necessary tools for vaccination. 2.Placing the ice bag under the device. 3.Selecting injection point. 4.Placing the Buzzy device near the injection point where the needle penetrates (5 cm above the penetration point). 5.The wider end of the device is put parallel to penetration point. 6.The device is fixed by the vaccinator. 7.15 seconds before vaccination, the “switch on” button on the device is pushed. 8.Vaccine injection according to the clinic’s protocol. 9.Switching off the device after injection. 10.Disinfecting the device and ice bag (if it is not disposable) using cotton and 70% alcohol.

Category

N/A

2

Description

placebo group: 1. Preparing buzzy device and other necessary tools for vaccination.2. Selecting injection point.3. Placing the buzzy device near the injection point where the needle penetrates (5 cm above the penetration point).4. The wider end of the device is put parallel to penetration point.5. The device is fixed by the vaccinator. 6. Vaccine injection according to the clinic’s protocol. 7. Disinfecting the device and ice bag (if it is not disposable) using cotton and 70% alcohol.

Category

N/A

3

Description

Control group:1. The vaccinator washes their hand with soap before injection2. Injection point must be disinfected using cotton and 70% alcohol in circle shapes and from the center outward. The vaccination should be done after complete evaporation of the alcohol.3. Previously prepared alcohol-stained cottons must not be used.4. DPT vaccine (triple vaccine) is injected in left Deltoid muscle and is done as deep tissue injection. 5. To inject the DPT vaccine, syringe size G23 is used. ** in control group, vaccination procedure will be as the clinic’s normal routine.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Abdollahi health center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Maryam Khoshqadam

Position
MS.pediatric nursing student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available