

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effects of hand-pressure, combination of vibration and cold, and routine infusion on pain induced by vaccine injection in 4-month-old children

Protocol summary

Study aim

Comparing the effects of hand-pressure, combination of vibration and cold, and routine infusion on pain induced by vaccine injection in 4-month-old children

Design

Ninety 4-month-old infants referring to Tohid Comprehensive Health Services Center in Birjand and eligible for inclusion in the study will be selected via convenience sampling method and randomly assigned into three groups of hand pressure, vibration and cold, and control.

Settings and conduct

In this double-blind study, the research setting will be Tohid Center of Comprehensive Health Services in Birjand. There are two intervention groups and one control group. In addition to the participants who are unaware of their allocations, two individuals who are not aware of the objectives of the project will check the videos and review the variables of the study after the sampling is completed.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: Four-month-old children; guardian consent for participation in the study; referral to receive the pentavalent vaccine; and term baby at birth (37-42 weeks). Main exclusion criteria: Consumption of analgesics by the child and mother during 48 hours before intervention; history of injections other than post-birth vaccine and screening tests.

Intervention groups

Intervention group 1 (hand pressure): After placing the child on the vaccination bed, hand pressure is applied to the injection site with the thumb, such that the thumb will be posited 0.5 centimeters above the injection site, and the pressure is applied until tissue resistance is observed and the thumb whitening is occurred. The pressure is applied from 10 seconds before until the end of the injection. Intervention group 2 (cold vibration): A

device inducing vibration and cold called Buzzy is placed 0.5 centimeters above the injection site and after 10 seconds, the injection is performed. Control group: The children will be vaccinated according to the routine procedure.

Main outcome variables

Pain severity; crying duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N46**

Registration date: **2018-08-30, 1397/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-30, 1397/06/08**

Update count: **0**

Registration date

2018-08-30, 1397/06/08

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 56 3239 5680

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01
Expected recruitment end date
 2018-10-23, 1397/08/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparing the effects of hand-pressure, combination of vibration and cold, and routine infusion on pain induced by vaccine injection in 4-month-old children

Public title
 Impact of hand-pressure and combination of vibration and cold on pain

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Four-month-old children guardian consent for participation in the study term baby at birth (37-42 weeks) referral to receive the pentavalent vaccine normal growth curve between the 5th and 95th percentiles children who are calm, awake, and without crying The baby's diaper should be dry
Exclusion criteria:
 Consumption of analgesics by the child and mother from 48 hours before intervention history of injections other than post-birth vaccine and screening tests history of surgery and hospitalization Cerebral palsy or mental retardation Acute or chronic illness

Age
 From **4 months** old to **4 months** old

Gender
 Both

Phase
 1-2

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description
 The allocation is via random blocks such that in each block, there will be three individuals. The first person will choose one of the three envelopes and will be placed in one of the three groups, and the other two will then be drawn into the other two groups by the same token.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 In addition to the participants who are unaware of their allocations, two individuals who are not aware of the objectives of the project will check the videos and review the variables of the study after the sampling is completed.

Placebo
 Not used
Assignment
 Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.BUMS.REC.1397.50

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

pain severity

Timepoint

15 seconds after injection for 1 minute

Method of measurement

FLACC Behavioral Pain Assessment Scale

2

Description

Crying duration

Timepoint

From the injection moment to the end of crying

Method of measurement

stopwatch

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 (hand pressure): After placing the child on the vaccination bed, hand pressure is applied to the injection site with the thumb, such that the thumb will be posited 0.5 centimeters above the injection site, and the pressure is applied until tissue resistance is observed and the thumb whitening is occurred. The pressure is applied from 10 seconds before until the end of the injection.

Category

Prevention

2

Description

Intervention group 2 (cold vibration): A device inducing vibration and cold called Buzzy is placed 0.5 centimeters above the injection site and after 10 seconds, the injection is performed.

Category

Prevention

3

Description

Control group: The children will be vaccinated according to the routines of the center.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Comprehensive Health Services Center

Full name of responsible person

Azar Sajed

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Valiasr St., Mehrshahr

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Azar Sajed

Position

MSc Student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Instructor

Latest degree

Master

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Person responsible for updating data

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Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

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Translator

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

When the extracted paper is published and for 6 months

To whom data/document is available

for researchers

Under which criteria data/document could be used

research purposes

From where data/document is obtainable

personal correspondence with the corresponding author

What processes are involved for a request to access data/document

email

Comments