Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Hugo point pressure massage with and without ice on pain due to Pentavalent vaccine in infants

Protocol summary

Summary

Purposes: the purpose of this study is comparing the effect of Hugo point compressive massage with and without ice on the pain resulted from Pentavalent vaccine in Infants. Study design: 72 two-month healthy infants who referred to Fayazbakhs public health center, Gonabad, for vaccination were attributed to three groups of Hugo point massage with ice, Hugo point massage without ice, and control group randomly (24 persons per group). The inclusion criteria are: admitting for vaccination in due time or with one week delay, Infants being in the normal weight and height percentile and no consumption of anti-pain drug the night before vaccination.Exclusion critaria: any kind of problem in vaccination procedure (injection repetition, selecting unsuitable location, injection angle, injection depth, vaccination volume). Method: relative intervention will be performed with each group five minutes before vaccination so that Hugo point of right hand was pressurized for one minute using soft part of the thumb rotationally and in a counter clockwise manner with medium pressure in first test group and/or ice cube covered in plastic glove and one-layer cotton cloth for second test group; the intervention is repeated twice after 30s relaxation. No intervention is performed in control group. Pain level will be measured before and after each intervention. Finally, resulted findings of three groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052127982N1**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name
Parisa Atayee
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Gonabad University of Medical Sciences
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Iran (Islamic Republic of)
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+98 51 5722 5027
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atayee.p@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Gonabad University of Medical Sciences

Expected recruitment start date

2016-05-29, 1395/03/09

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Hugo point pressure massage with and without ice on pain due to Pentavalent vaccine in infants

Public title

Comparison of the effect of Hugo point pressure massage with and without ice on pain due to vaccination

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Parents should agree on engaging the infant in the study. Infants who attend for the first round of Pentavalent vaccination mostly with one week delay. Infants should be in the normal weight and height percentile when receiving the vaccination. Auxiliary temperature should be between 36.5 and 37.5oC. Infants should be relax before vaccination. There should be no consumption of acetaminophen or any other anti-pain drug the night before vaccination. They should be fed 2-3 hours before vaccination. There should be no problem or insomnia before injection based on descriptions from her/his mother.Exclusion criteria: parents leave the study. Polio drop is given before vaccination. Occurrence of any problem during Pentavalent vaccination (injection repeat, selecting unsuitable location, injection angle, injection depth, wrong selection of the vaccine, vaccine volume), crying and uneasiness 5s before vaccination or after video control

Age

From **2 months** old to **2 months** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling method: it will be done through convenience sampling and random allocation using permutation blocking method. Blinding: intervention and control groups include two-month infants who are naturally blind in terms of the intervention target.(MBPS tool is used to measure pain scale based on three criteria of face change, crying and body movements of infants.) Pain scale is measured by someone not aware of the type of intervention. Data are also analyzed by someone not aware of the intervention and control groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City

Gonabad

Postal code

9691793718

Approval date

2016-05-11, 1395/02/22

Ethics committee reference number

IR.GMU.REC.1395.17

Health conditions studied

1

Description of health condition studied

Factors influencing health status and contact with health services

ICD-10 code

Z27.8

ICD-10 code description

Need for immunization against other combinations of infectious diseases

Primary outcomes

1

Description

pain due to vaccination

Timepoint

During 5 second before immunization to 15 second after

Method of measurement

Modified Behavioral Pain Scale (MBPS) in infants

Secondary outcomes

empty

Intervention groups

1

Description

Hugo point of the right hand will be massaged for 1 minute using ice cube covered in plastic glove and one-layer cotton cloth for second test group; the intervention is repeated twice after 30s relaxation

Category

Prevention

2

Description

Infants of the control group will be put on the bed without any intervention and based on the usual procedure of the center.

Category

Prevention

3

Description
Hugo point of the right hand will be massaged for 1 minute using soft part of the thumb in first test group and the intervention will be repeated twice after 30s relaxation.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fayazbakhs public health center

Full name of responsible person
Parisa Atayee

Street address
Emam khomeini street, Gonabad

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Gonabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Gonabad University of Medical Sciences

Full name of responsible person
Doctor Ali Mohammadpour

Street address
Vice chancellor for research,Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City
Gonabad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research,Gonabad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

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Position
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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty