

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

The comparison of injection order of the Diphtheria-Pertussis-Tetanus vaccine and Hepatitis B vaccine on pain response in infants

Protocol summary

Summary

This study was designed to compare the effect of injection order of the Diphtheria-Pertussis -Tetanus (DPT) vaccine and Hepatitis B vaccine on pain response in infants. This single-blind, randomized clinical trial study has been conducted on 140 infants referred to Seyedolshohada health care center of Zahedan. Inclusion criteria: healthy two month-old infants in both sexes with complete consciousness, no history of surgery or hospitalization and absence of chills, fever, diarrhea. Exclusion criteria: taking analgesic or sedative drug 24 hours before to vaccination by the infant or her mother. The samples have been randomly divided into two groups: Intervention and control groups. In the Intervention group, first 0.5 ml Hepatitis B vaccine manufactured by Pasteur Institute of Iran injected intramuscular and then 0.5 ml DTP vaccine manufactured by Pasteur Company of Indonesia injected intramuscular. In the control group the routine order administered. (First the 0.5 ml DTP vaccine injected intramuscular and then the 0.5 ml Hepatitis B vaccine injected intramuscular). Response to pain of infants evaluated immediately after vaccine injection until 15 seconds by unaware observer of the type of intervention through the Modified Behavioral Pain Scale (MBPS). Also, the duration of crying in seconds has been measured immediately after vaccine injection until infants to calm down or maximum to 3 minutes after injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070713889N1**

Registration date: **2013-12-22, 1392/10/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-22, 1392/10/01

Registrant information

Name

Hasan Robabi

Name of organization / entity

Zahedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-11-26, 1392/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of injection order of the Diphtheria-Pertussis-Tetanus vaccine and Hepatitis B vaccine on pain response in infants

Public title

Effect of injection order of the Diphtheria-Pertussis-Tetanus vaccine and Hepatitis B vaccine on pain in infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Healthy two month-old infants of both sexes with complete consciousness. 2. No history of surgery or hospitalization 3. Absence of chills, fever, diarrhea, etc. Exclusion criteria: taking analgesic or sedative drug 24 hours before vaccination by the infant or her mother.

Age

From **2 years** old to **3 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The is a single-blind, randomized clinical trial study, so that observer evaluating pain response was not aware of which vaccine had been administered. Random selection was performed through placing letters A and B in envelope which was numbered for each participant as follows: ask mother of infants select one of these letters, letters A and B indicated of Intervention and Control group respectively.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Vice Chancellor for research, Zahedan University of Medical Sciences -Dr Hesabi Square- Zahedan

City

Zahedan

Postal code

98167-43463

Approval date

2012-09-26, 1391/07/05

Ethics committee reference number

91-2531

Health conditions studied

1

Description of health condition studied

The Pain of vaccine

ICD-10 code

M79.6

ICD-10 code description

pain in limb

Primary outcomes

1

Description

Behavioral pain responses

Timepoint

Immediately after vaccine injection until 15 seconds

Method of measurement

Modified Behavioral Pain Scale (MBPS)

Secondary outcomes

1

Description

Duration of crying

Timepoint

Immediately after vaccine injection up to time infants calm down or, maximum up to 3 minutes after injection.

Method of measurement

Using stop watch(second)

Intervention groups

1

Description

Intervention group: First the 0.5ml Hepatitis B vaccine manufactured by Pasteur Institute of Iran injected intramuscularly and then the 0.5ml DTP vaccine manufactured by Pasteur Company of Indonesia injected intramuscularly.

Category

Prevention

2

Description

Control group: Routine order administered.(First the 0.5ml DTP vaccine manufactured by Pasteur Company of Indonesia injected intramuscularly and then the 0.5ml Hepatitis B vaccine manufactured by Pasteur Institute of Iran injected intramuscularly)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Syedoshohada Health Care Center

Full name of responsible person

Hasan Robabi

Street address

Syedoshohada Health Care Center - Shahid Rajaie str. Zahedan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Dr M.Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences - Dr Hesabi Square- Zahedan

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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

Vice chancellor for research, Zahedan 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

Contact**Name of organization / entity**

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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