

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 54 1243 6643

###### Email address

robabi@zaums.ac.ir

##### 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**

Zahedan

### 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

**City**

Zahedan

**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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Fatihe Kerman Saravi

**Position**

MSc/ Instructor of Nursing, Zahedan Nursing and Midwifery School

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### Person responsible for scientific inquiries

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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*