Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 on140 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

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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 administrated. 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
Seyedoshohada Health Care Center
Full name of responsible person
Hasan Robabi
Street address
Seyedoshohada Health Care Center - Shahid Rajaie str. Zahedan
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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
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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

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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