

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Clinical trial of evaluation of 18th month of age vaccines injection order (intramuscular first and then subcutaneous or subcutaneous first and then intramuscular) on pain of intramuscular injection of diphtheria, pertussis and tetanus vaccine

Protocol summary

Summary

This clinical trial will be done to answer this question that whether intramuscular injection of diphtheria, pertussis and tetanus (DPT) vaccine first and then subcutaneous injection of measles, mumps and rubella (MMR) vaccine or subcutaneous injection of MMR vaccine first and then intramuscular injection of DPT vaccine, can cause less pain of DPT vaccine intramuscular injection. In a clinical trial, sixty healthy 18 month old children who will be referred for vaccination to Primary Health Care Center of Akbari in Yazd, Iran will be randomly distributed into two groups. In group I, intramuscular DPT vaccine will be injected first and then subcutaneous injection of MMR will be done and in group II, children will receive subcutaneous injection of MMR vaccine first and then intramuscular injection of DPT vaccine. In all of them, vaccines will be injected in similar conditions and by a trained person. Primary outcomes include pain score during DPT vaccine injection, pain score during MMR vaccine injection and obtaining of pain score of less than four during DPT vaccine injection. Pain score when the needle is inserted to the skin will be assessed based on Modified Behavioral Pain Scale. Secondary outcome will be duration of baby crying during DPT vaccine injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409042639N14**

Registration date: **2014-10-10, 1393/07/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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Phone

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Expected recruitment start date

2014-08-26, 1393/06/04

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluation of 18th month of age vaccines injection order (intramuscular first and then subcutaneous or subcutaneous first and then intramuscular) on pain of intramuscular injection of diphtheria, pertussis and tetanus vaccine

Public title

Effect of the order of injecting 18th month of age vaccines on pain

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 18 months of age, being in a healthy medical condition and referring for vaccination to primary health care center Exclusion criteria: neurodevelopmental delay, severe congenital malformation and receiving sedative hypnotic drugs within the past 24 hours

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The children in this trial will be randomized by random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Street address

central building of university, Bahonar square

City

Yazd

Postal code

Approval date

2014-08-24, 1393/06/02

Ethics committee reference number

17/1/107183/پ

Health conditions studied

1

Description of health condition studied

vaccination

ICD-10 code

Z27

ICD-10 code description

Need for immunization against combinations of infectious diseases

Primary outcomes

1

Description

pain score during diphtheria, pertussis and tetanus (DPT) vaccine injection

Timepoint

time of needle insertion to skin

Method of measurement

Modified Behavioral Pain Scale table

2

Description

pain score during measles, mumps and rubella (MMR) vaccine injection

Timepoint

time of measles, mumps and rubella (MMR) vaccine injection

Method of measurement

Modified Behavioral Pain Scale table

3

Description

obtaining of pain score of less than four during diphtheria, pertussis and tetanus (DPT) vaccine injection

Timepoint

time of diphtheria, pertussis and tetanus (DPT) vaccine injection

Method of measurement

Modified Behavioral Pain Scale table

Secondary outcomes

1

Description

duration of baby crying after injection of DPT vaccine

Timepoint

every 10 seconds after vaccine injection until stopping of crying

Method of measurement

by chronometer

Intervention groups

1

Description

intramuscular injection of a single dose of DPT

(diphtheria, pertussis and tetanus) vaccine and then subcutaneous injection of a single dose of combination of measles, mumps and rubella vaccines

Category

Prevention

2**Description**

subcutaneous injection of a single dose of combination of measles, mumps and rubella vaccines and then intramuscular injection of a single dose of DPT (diphtheria, pertussis and tetanus) vaccine

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Primary Health Care Center of Akbari

Full name of responsible person

Dr.Hossein Gholami

Street address

Timsar Fallahi Street , Emam Hassan square,Safaeeh,Yazd, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

Full name of responsible person

Dr.Fatemah Ezoddini

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central building of university , Bahonar Square

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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

Research Deputy of Shahid Sadoughi University of Medical Sciences , Yazd, Iran

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**

Shahid Sadoughi University of Medical Sciences , Yazd , Iran

Full name of responsible person

Dr. Hosein Gholami

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Pediatric resident

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Full name of responsible person

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Position

Pediatric Neurologist , Associate professor

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Position

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Web page address**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