

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3822 4000

###### Email address

fallah@ssu.ac.ir

##### 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

**City**

Yazd

**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

**Street address**

central building of university , Bahonar Square

**City**

Yazd

**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

**Position**

Pediatric resident

**Other areas of specialty/work****Street address**

Shahid Sadoughi Hospital , Ave - Sina Blvd, Shahid Ghandi Blvd, Yazd, I.R.Iran

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr.Razieh Fallah

**Position**

Pediatric Neurologist , Associate professor

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

Dr.Razieh Fallah

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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*