

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The Effect of Syringe Type on Adverse Effect Following DTP Vaccine Immunization, a Randomized Clinical Trial.

#### Protocol summary

##### Summary

Although vaccines are safe biological material, mild adverse effects following immunization are common and severe complications may occur rarely. Early recognition and removal of difficulties in immunization have an important role in maintain of high coverage of vaccination and achieving to goals of program. This study is designed to determine the role of syringe type in adverse effect following DTP vaccination. All children who must receive DTP vaccine and are eligible to enroll the study will be investigated, after training of staff in two primary health centre of Shahroud city. The demographic data of the child including age, sex, date of birth, previous immunization history, and ... Record by trained health care workers. Before injection of vaccine they ask the syringe type which must be used from an expert in shahroud health center by telephone. The health expert determines the syringe type (A or B) according to randomization protocol after register the child name. All children in the second, fourth and sixth after vaccination are being investigated for adverse effects of DTP. The main outcome for investigation in this study is Sever local reaction. all children who have adverse effects examine by a physician to determine its type and severity. Follow up examination will perform at children home in the same day if they denied going to examination center. After randomization decoding, the rate of adverse events in both groups will be analyzed.

#### General information

##### Acronym

AEFI

##### IRCT registration information

IRCT registration number: **IRCT201107317171N1**

Registration date: **2011-10-09, 1390/07/17**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-10-09, 1390/07/17

##### Registrant information

###### Name

Mohammad Hassan Emamian

###### Name of organization / entity

Shahroud University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 27 3339 5054

###### Email address

emamian@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahroud University of Medical Sciences

##### Expected recruitment start date

2012-01-15, 1390/10/25

##### Expected recruitment end date

2012-06-09, 1391/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Syringe Type on Adverse Effect Following DTP Vaccine Immunization, a Randomized Clinical Trial.

##### Public title

The Effect of Syringe Type on Adverse Effect Following Immunization.

##### Purpose

Health service research

## **Inclusion/Exclusion criteria**

All children who are eligible for DTP vaccination can be registered in this study. every eligible child is not enrolled in study If DTP vaccination is contraindicated, his/her parents denied to sign informed consent or the child is not accessible for follow up of AEFI (adverse effects following immunization ).

### **Age**

To **6 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **1000**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Triple blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Shahroud University of Medical Sciences

##### **Street address**

7 tir SQ, Shahroud university of Medical Sciences

##### **City**

Shahroud

##### **Postal code**

#### **Approval date**

2011-08-20, 1390/05/29

#### **Ethics committee reference number**

900/17

## **Health conditions studied**

### 1

#### **Description of health condition studied**

sever local reaction following immunization

#### **ICD-10 code**

T88.0

#### **ICD-10 code description**

Infection following immunization

### 2

#### **Description of health condition studied**

sever local reaction following immunization

#### **ICD-10 code**

T88.1

#### **ICD-10 code description**

Other complications following immunization, not elsewhere classified

## **Primary outcomes**

### 1

#### **Description**

erythema

#### **Timepoint**

days 2, 4 and 6 following immunization

#### **Method of measurement**

By health care professional and/or physician

### 2

#### **Description**

oedema

#### **Timepoint**

days 2, 4 and 6 following immunization

#### **Method of measurement**

By health care professional and/or physician

### 3

#### **Description**

pain

#### **Timepoint**

days 2, 4 and 6 following immunization

#### **Method of measurement**

By health care professional and/or physician

### 4

#### **Description**

fever

#### **Timepoint**

days 2, 4 and 6 following immunization

#### **Method of measurement**

By health care professional and/or physician

## **Secondary outcomes**

### 1

#### **Description**

sever local reaction AND Injection-Site Abscess

#### **Timepoint**

Days 2, 4, and 6 after immunization

#### **Method of measurement**

By health care professional and/or physician

## **Intervention groups**

## 1

### Description

DTP vaccine is administrated by type B syringe

### Category

Other

## 2

### Description

DTP vaccine is administrated by type A syringe

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mohammadi health care center

##### Full name of responsible person

Nagieh Saadi

##### Street address

##### City

Shahroud

### 2

#### Recruitment center

##### Name of recruitment center

Shahid Rajaei (Azima) health care center

##### Full name of responsible person

Zahra Behzad Javidkhah

##### Street address

##### City

Shahroud

### 3

#### Recruitment center

##### Name of recruitment center

Updated, 2012-08-09: Shahrake Farhangian health care center

##### Full name of responsible person

Updated, 2012-08-09: Nadieh Nazemi

##### Street address

Updated, 2012-08-09: Shahrake Farhangian

##### City

Updated, 2012-08-09: Shahroud

### 4

#### Recruitment center

##### Name of recruitment center

Added at 2012-11-18: Shahid Sharif

##### Full name of responsible person

Added at 2012-11-18: Roghieh Damavandi

##### Street address

Added at 2012-11-18: Shahrake Emam

##### City

Added at 2012-11-18: Shahroud

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Ahmad Khosravi

##### Street address

7 Tir SQ. Shahroud university of medical sciences

##### City

Shahroud

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Shahroud 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

Shahroud university of Medical Sciences

##### Full name of responsible person

Mansooreh Fateh, MD, MPH

##### Position

Head of Shahroud CDC

##### Other areas of specialty/work

##### Street address

Ferdoosi St. Shahroud Health Center

##### City

Shahroud

##### Postal code

##### Phone

+98 27 3222 0062

##### Fax

##### Email

fateh@shmu.ac.ir; fateh45908@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Mohammad Hassan Emamian, MD, PhD

**Position**

Head of Statistics and IT department / Epidemiologist

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

7 Tir SQ. Shahroud University of Medical Sciences

**City**

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+98 27 3339 5054

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emamian@shmu.ac.ir; pishgiri@yahoo.com

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

Shahroud university of Medical Sciences

**Full name of responsible person**

Mansoorah Fateh, MD, MPH

**Position**

Head of Shahroud CDC

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

Ferdoosi St. Shahroud Health Center

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Shahroud

**Postal code****Phone**

+98 27 3222 0062

**Fax****Email**

fateh@shmu.ac.ir

**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*