

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: Nadiieh 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

Shahroud

Postal code**Phone**

+98 27 3339 5054

Fax**Email**

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

City

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