

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Immunogenicity and short term reactogenicity of cellular DTP vaccine in Iranian children

Protocol summary

Summary

In this prospective study, 558 infants and 672 children aged 4-6 years were injected with DTWP vaccine manufactured by Razi Institute of Iran (DTWP-Razi) or Sanafi-Pasteur of France (DTWP-Pasteur). All children received DTWP vaccine at 2, 4, and 6 months of age (Primary vaccination) or 4-6 years of age (booster vaccination), following the national vaccination schedule of Iran. In children, blood samples were collected before and 2-4 weeks after the vaccination and in infants 2-4 weeks after the 3rd dose (6th month) of vaccination. The immunogenicity of the vaccines was assessed by ELISA using commercial kits. Antibody against protective antigens of pertussis, including pertussis toxin (PT), filamentous haemagglutinin (FHA) and pertactin (PRN) was measured by designed ELISA assay. Reactogenicity was assessed by the parents for 7 days post-vaccination using diary cards. Local (pain, redness and swelling) and systemic (fever, loss of appetite, gastrointestinal symptoms, vomiting and eczema) side effects were recorded daily.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902072471N2**

Registration date: **2010-06-14, 1389/03/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-14, 1389/03/24

Registrant information

Name

Saeed Zarei

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2020

Email address

szarei@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of food and drugs, Ministry of Health and Medical Education

Expected recruitment start date

2005-03-21, 1384/01/01

Expected recruitment end date

2007-09-23, 1386/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immunogenicity and short term reactogenicity of cellular DTP vaccine in Iranian children

Public title

Immunogenicity and short term reactogenicity of cellular DTP vaccine in Iranian children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy children Exclusion criteria: Incomplete vaccination card, immunodeficiency disease, severe asthma and allergy

Age

To **6 years** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **600**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Center

Street address

Avicenna Research Institute, Shahid Beheshti
University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Approval date

empty

Ethics committee reference number

83/1106

Health conditions studied

1

Description of health condition studied

DTP

ICD-10 code

Z27.1

ICD-10 code description

Need for immunization against diphtheria-tetanus-
pertussis, combined [DTP]

Primary outcomes

1

Description

Antibody response against Diphtheria, Tetanus and
Pertussis

Timepoint

one month

Method of measurement

ELISA

Secondary outcomes

1

Description

Comparison DTP vaccine reactogenicity

Timepoint

Immediate after vaccine

Method of measurement

Checking by parents

Intervention groups

1

Description

Injecting vaccine that is approved by WHO (control
group)

Category

Treatment - Drugs

2

Description

Injecting Iranian Vaccine (case group)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

East Health Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of food and drugs, Ministry of Health and
Medical Education

Full name of responsible person

Dr. Dinarvand

Street address

Fakhrerazi st, Enghelab sq

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of food and drugs, Ministry of Health and Medical Education

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

Avicenna Research institute

Full name of responsible person

Dr. Fazel Shokri

Position

PhD

Other areas of specialty/work

Street address

Avicenna Research institute, Shahid Beheshti University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 21 2243 2020

Fax

+98 21 2243 2021

Email

fazshok@yahoo.com

Web page address

Avicenna Research Institute, Shahid Beheshti University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 982122432020

Fax

+98 21 2243 2021

Email

fazshok@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Avicenna Research institute

Full name of responsible person

Dr. Saeed Zarei

Position

MD

Other areas of specialty/work

Street address

Avicenna Research institute, Shahid Beheshti University.Evin.Shahid Chamran highway

City

Tehran

Postal code

19615-1177

Phone

+98 21 2243 2020

Fax

+98 21 2243 2021

Email

szarei@avicenna.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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Dr. Fazel Shokri

Position

PhD

Other areas of specialty/work

Street address