

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of the immunogenicity and safty of the pentavalent vaccine used in national immunization program compared with the same vaccines from the other pharmaceutical companies

Protocol summary

Summary

In this study we want to evaluate immunogenicity and safety of the Pentavalent vaccine used in national immunization programs compared with the same vaccines from two other pharmaceutical companies in appropriate time interval before and after vaccination. The comparison groups are children using pentavalent vaccine of Sanofi Pasteur (SHAN5) and biofarma company which have prequalification (PQ) from WHO. And these two groups are being compared with children using Indian vaccine from Serum Institute in regards of antibody production against components of vaccine. In this way we will promote and expand the national vaccination programm after assurance of this vaccine efficacy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051222234N1**

Registration date: **2016-09-05, 1395/06/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-05, 1395/06/15

Registrant information

Name

Maryam Rajabnejad

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 6941

Email address

m_rajabnejad@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Institute for Medical Research Development

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the immunogenicity and safty of the pentavalent vaccine used in national immunization program compared with the same vaccines from the other pharmaceutical companies

Public title

Evaluation of the immunogenicity of the pentavalent vaccine

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. Healthy 2 -month-old infant boy or girl who is referred for routine vaccination 2. Infant disease is not identified at the time of visit 3. Upon arriving at the physical examination is normal nursing 4. Parents of infants in the study were successful login and sign the informed consent form 5. infants with gestational age of 38 weeks of a normal pregnancy and birth weight ≥ 2.5 kg Exclusion criteria: 1. The use of any

vaccine or drug, vaccine research studies except during the study period or 30 days prior to study entry 2. History of blood transfusions or blood products or immunoglobulin consumption 3. History of heart, respiratory, kidney, liver and blood disease 4. Known genetic or congenital immune deficiency 5. Participation in other clinical studies

Age

From **2 months** old to **7 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1200**

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**

National Institute for Medical Research Development

Street address

National Institute for Medical Research Development,
Azadi st.

City

Tehran

Postal code**Approval date**

2016-04-04, 1395/01/16

Ethics committee reference number

IR.NIMAD.REC.1395.002

Health conditions studied**1****Description of health condition studied**

pentavalent vaccine

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Determination of antibody (IgG) titer against each of components of the vaccine (Diphtheria, Tetanus, Pertussis, Hepatitis B and H.influenzae) following vaccination with pentavalent vaccine in ages of 2, 4 and 6 months

Timepoint

2, 7 months after intervention

Method of measurement

ELISA

Secondary outcomes**1****Description**

Safety of pentavalent vaccine

Timepoint

Adverse event of vaccine

Method of measurement

Observation

Intervention groups**1****Description**

group 1 (case): give biofarma vaccine

Category

Prevention

2**Description**

group 1(control): give routine pentavalent vaccine

Category

Prevention

3**Description**

group 2 (case) : give shan5 vaccine

Category

Prevention

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

Mahdiye hospital

Full name of responsible person**Street address**

shoush - fadaiyan eslam ave - shishegar khane

City

Tehran

2

Recruitment center

Name of recruitment center

East Tehran Health Center

Full name of responsible person**Street address**

emamat - jadidi ave - aboureyhan

City

Tehran

3

Recruitment center

Name of recruitment center

Ershad vaccination center

Full name of responsible person**Street address**

shariati - eshraghi ave-

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

Dr Esalatmanesh

Street address

National Institute for Medical Research Development,
Azadi Ave., Between Gharib and Eskandari Ave.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

National Institute for Medical Research Development

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**

Pediatric Infections Research Center

Full name of responsible person

Maryam Rajabnejad

Position

Pediatrician

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

Mofid hospital

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Fax**Email**

pediatric_center@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Pediatric Infections Research Center

Full name of responsible person

Sedighe Rafiei Tabatabaei

Position

Subspecialist of infectouse disease

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

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Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Pediatric Infections Research Center

Full name of responsible person

Maryam Rajabnejad

Position

Pediatrician

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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