

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Phase IV, Multicenter, Open label, Post marketing study to assess the immunogenicity and safety of DTPw-Hep B-Hib (PRP-T) vaccine (pentavac) (adsorbed) manufactured by Serum Institute of India Ltd. in infants aged 2-7 months in Alborz Province, Iran

Protocol summary

Summary

This is an open-label, single arm post marketing study in infants aged 2-7 months. Infants who meet inclusion criteria will receive Pentavalent (DTwP-HB-Hib) vaccine (adsorbed)/Pentavac for active immunization against Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib infections. Each infant receives 0.5ml Pentavac vaccine as an intramuscularly injection into the antero-lateral aspect of thigh at 2, 4, 6 months of age. Two blood sample will be taken from enrolled infants for measurement of antibody serum titer against Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib separately, the first sample will be taken immediately before first dose injection of vaccine and the second sample will be taken 4-6 weeks after third dose injection. Immunogenicity evaluation will be performed by determination the rate of sero-protection occurrence in vaccinated infants against each part of this conjugated vaccine separately, based on comparison of serum titer antibodies results in second blood sample with the standard cut off values for sero-protection in utilized kit. Safety evaluation will be performed by determination the rate of local and systemic adverse events occurrence during two period of times, during 30 minutes immediately after each vaccine injection (reactogenicity) when vaccinated infant is observed directly by responsible physician and till one month after each vaccine injection by infant's parents.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042027498N1**

Registration date: **2016-06-10, 1395/03/21**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-10, 1395/03/21

Registrant information

Name

Mahmood Faramarzi

Name of organization / entity

Research Center of Pediatric Infectious Diseases

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 6049

Email address

Faramarzimahmood@yahoo.com

Recruitment status

Recruitment complete

Funding source

Barkat Foundation

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Phase IV, Multicenter, Open label, Post marketing study to assess the immunogenicity and safety of DTPw-Hep B-Hib (PRP-T) vaccine (pentavac) (adsorbed) manufactured by Serum Institute of India Ltd. in infants aged 2-7 months in Alborz Province, Iran

Public title

Post marketing study to assess the immunogenicity and safety of DTPw-Hep B-Hib (PRP-T) vaccine (pentavac)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy infants of either sex aged 2 months at the time of first dose injection; Free of obvious health problems as established by medical history and clinical exam before entering into the study; Born after normal gestational age (36-42 weeks); Written, explained, and signed informed consent form of infant's parents; Born to sero-negative HBsAg mothers (based on pregnancy documents or mother declaration); Born to sero-negative HIV mothers (based on pregnancy documents or mother declaration); The infant should be receive vaccination of 2/4/6 months at the same clinic and should be available after last vaccination up to two months
Exclusion criteria: Use of any investigational drug or vaccine other than Pentavac during the study period or within 30 days prior the first vaccine dose; Administration of immunoglobulins or any other blood products since birth; Administration of a routine vaccine 30 days before or during the study period except BCG and OPV vaccine; History of significant and persistent hematologic, hepatic, renal, cardiac or respiratory disease; Evidence of any acute infection or fever; Axillary temperature $\geq 38.5^{\circ}\text{C}$; History of neurological disorders or seizure; History of allergic disease or reactions which is possibly exacerbated by any component of vaccine; Confirmed immunosuppression including HIV infection; Any congenital or hereditary immunodeficiency; Simultaneous participation in any other clinical study

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **691**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical University (IUMS)

Street address

Besides Milad Tower, Hemmat Expressway

City

Tehran

Postal code

-

Approval date

2015-12-15, 1394/09/24

Ethics committee reference number

IR.IUMS.REC.1394.26616

Health conditions studied

1

Description of health condition studied

Diphtheria vaccine

ICD-10 code

Y58.5

ICD-10 code description

Diphtheria vaccine

2

Description of health condition studied

Tetanus vaccine

ICD-10 code

Y58.4

ICD-10 code description

Tetanus vaccine

3

Description of health condition studied

Pertussis vaccine

ICD-10 code

Y58.6

ICD-10 code description

Pertussis vaccine

4

Description of health condition studied

Haemophilus influenzae Vaccine

ICD-10 code

P23.6

ICD-10 code description

Haemophilus influenzae Vaccine

5

Description of health condition studied

Hepatitis B Vaccine

ICD-10 code

Y59.0

ICD-10 code description

Primary outcomes

1

Description

Anti-Diphtheria antibody

Timepoint

One month after intervention

Method of measurement

Immunoassay

2

Description

Anti-Tetanus antibody

Timepoint

One month after intervention

Method of measurement

Immunoassay

3

Description

Anti-Hepatitis B antibody (HbsAb)

Timepoint

One month after intervention

Method of measurement

Immunoassay

4

Description

Anti-Haemophilus influenzae antibody

Timepoint

One month after intervention

Method of measurement

Immunoassay

5

Description

Anti-Pertussis Antibody

Timepoint

One month after intervention

Method of measurement

Immunoassay

Secondary outcomes

1

Description

Adverse clinical symptoms of vaccination

Timepoint

One month after vaccination

Method of measurement

Evaluation of Symptoms

Intervention groups

1

Description

Two blood sample will be taken from enrolled infants for measurement of antibody serum titer against Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib separately, the first sample will be taken immediately before first dose injection of vaccine and the second sample will be taken 4-6 weeks after third dose injection.

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shahid Turkian Health Center

Full name of responsible person**Street address****City**

Karaj

2

Recruitment center**Name of recruitment center**

Hesarak Health Center

Full name of responsible person**Street address****City**

Karaj

3

Recruitment center**Name of recruitment center**

Shohadaey Meshkin-Shahr Health Center

Full name of responsible person**Street address****City**

Karaj

4

Recruitment center**Name of recruitment center**

Shohadaey Fardis Health Center

Full name of responsible person**Street address****City**

Karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Biosun Farmed (Barkat Foundation)

Full name of responsible person

DR. Taghavian

Street address

No.6, St No.8, Bokharest St

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Biosun Farmed (Barkat Foundation)

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

Research Center of Pediatric Infectious Diseases

Full name of responsible person

Mahmood Faramarzi

Position

MS.c. of Medical Immunology

Other areas of specialty/work

Street address

Sattar khan St, Niayesh St, Hazrat-e-Rasool Akram Hospital

City

Tehran

Postal code

Phone

+98 21 6651 6049

Fax

Email

Faramarzimahmood@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Center of Pediatric Infectious Diseases

Full name of responsible person

Hossein Masoumi-Asl

Position

MD of Pediatric Infectious Diseases

Other areas of specialty/work

Street address

Sattar khan St, Niayesh St, Hazrat-e-Rasool Akram Hospital

City

Tehran

Postal code

Phone

+98 21 6651 6049

Fax

Email

Dr_masoumiasl@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Mahmood Faramarzi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 913 841 1980

Fax

Email

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