Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The phase 3, randomized, two-arm, parallel group, double-blind, active controlled non-inferiority clinical trial evaluating the immunogenicity and safety of the 13-valent pneumococcal vaccine (PneumoConj®- manufactured by Nivad Pharmed Salamat), compared to the 13-valent pneumococcal vaccine (Prevnar®- manufactured by Pfizer) as the reference product, in infants aged 8 ± 2 weeks

Protocol summary

Study aim

The evaluation of non-inferiority of the 13-valent pneumococcal vaccine (PneumoConj®) in comparison to the Prevnar® in terms of immunogenicity in healthy infants aged 8 ± 2 weeks.

Design

A phase 3, Randomized, Two-arm, Double-blind, Parallel-group, Active-controlled clinical trial with sample size of 324

Settings and conduct

A Phase III, Double-blind (Investigator and Participant), Two-arm, Active-controlled, with a 1:1 allocation and sample size of 324, non-inferiority clinical trial evaluating the immunogenicity and safety of the 13-valent pneumococcal vaccine, In the health center of Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Infants aged 8±2 weeks who are in good general health Exclusion criteria: History of previous vaccination against pneumococcus

Intervention groups

The 13-valent pneumococcal vaccine (PneumoConj®) at a dose of 0.5 milliliters at 2, 4, and 6 months of age in infants, with a booster dose administered at 12 to 15 months of age The 13-valent pneumococcal vaccine (Prevnar®) at a dose of 0.5 milliliters at 2, 4, and 6 months of age in infants, with a booster dose administered at 12 to 15 months of age

Main outcome variables

1. IgG seroresponse rate 2. IgG GMC ratio

General information

Reason for update

The ethics code was incorrectly entered in the initial submission and has been corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240626062259N1**
Registration date: **2024-07-30, 1403/05/09**
Registration timing: **prospective**

Last update: **2025-12-24, 1404/10/03**
Update count: **1**

Registration date

2024-07-30, 1403/05/09

Registrant information

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Name of organization / entity
Nivad Pharmed Salamat
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-31, 1403/05/10

Expected recruitment end date

2024-08-31, 1403/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The phase 3, randomized, two-arm, parallel group, double-blind, active controlled non-inferiority clinical trial evaluating the immunogenicity and safety of the 13-valent pneumococcal vaccine (PneumoConj®- manufactured by Nivad Pharmed Salamat), compared to the 13-valent pneumococcal vaccine (Prevnar®- manufactured by Pfizer) as the reference product, in infants aged 8 ± 2 weeks

Public title

Evaluation of immunogenicity and safety of the 13-valent pneumococcal vaccine (PneumoConj®- manufactured by Nivad Pharmed Salamat), compared to the 13-valent pneumococcal vaccine (Prevnar®- manufactured by Pfizer) as the reference product, in infants aged 8 ± 2 weeks

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Infants aged 8±2 weeks. Good general health (confirmed through clinical examinations and medical records, e.g., normal growth curve, normal head circumference). Parents willing to provide informed and voluntary written consent for their infant's participation in the study. Ability to accompany their infant for study visits and follow-up sessions.

Exclusion criteria:

History of previous vaccination against pneumococcal strains. History of severe hypersensitivity reactions following vaccine injection. Infants with congenital abnormalities, growth disorders, genetic defects, or severe malnutrition. Infants with pathological jaundice lasting 2 to 4 weeks and recurring. History of confirmed respiratory infection at clinic or serology, especially due to Streptococcus pneumoniae. History of HIV infection in mother or infant. Presence of thrombocytopenia (platelets less than 150,000) or other coagulation disorders. Axillary temperature above 37.8 degrees Celsius within 72 hours prior to the study. Family history of seizures, epilepsy, or encephalopathy in first-degree relatives of the infant. Preterm and low birth weight infants (born before 37 weeks of gestation with birth weight less than 2.5 kilograms). Family history of congenital or hereditary immunodeficiency in first-degree relatives. Receipt of vaccines outside of the national immunization schedule or medications prohibited simultaneously. Conditions deemed by the principal investigator to prevent participation. Participation in other clinical vaccine studies.

Age

From **42 days** old to **70 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **324**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation of infants to intervention groups is done by stratified randomization by www.sealedenvelope.com. The strata in this study are the centers and, in each stratum, random numerical sequences will be created in the form of permuted blocks. For this purpose, random blocks with block size 2 and 4 (equal number of each group are present in each block) and with a ratio of 1:1 will be done for a total of 324 infants. When randomization is done, each infant will receive a unique code by which he will be identified throughout the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the control and test drug packages are completely identical and are identified using random codes, the parents of the participants will not be aware of the type of vaccine their child has received. Additionally, study data will be anonymized based on the unique identification codes assigned to each participant at the start of the study. This ensures that the study remains blinded for both the doctor and the evaluator. Similarly, the samples and laboratory results will be identified and reported only with the codes corresponding to each participant, without any names.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee / Ministry-level Research Ethics Working Group

Street address

13th Floor, Block A, Central Headquarters, Ministry of Health and Medical Education, Simaye Iran Street, between South Flamak and Zarafshan, Shahrak-e Ghods (West), Tehran, Iran

City

Tehran

Province

Tehran

Postal code
1417653761
Approval date
2024-04-16, 1403/01/28
Ethics committee reference number
IR.NREC.1403.002

Health conditions studied

1

Description of health condition studied
Otitis media prevention / Pneumonia prevention
ICD-10 code
J13
ICD-10 code description
Pneumonia due to Streptococcus pneumoniae

Primary outcomes

1

Description
IgG seroresponse rate against different serotypes after 5 months: IgG seroresponse rate against different serotypes after 5 months (one month after the third dose injection) compared to the control group.
Timepoint
One month after the third dose injection
Method of measurement
ELISA. Percentage of individuals with IgG antibody concentration above 0.35 micrograms per milliliter.

2

Description
IgG GMC ratio against different serotypes after 5 months: IgG GMC ratio against different serotypes after 5 months (one month after the third dose injection) in the candidate group compared to the control group.
Timepoint
One month after the third dose injection.
Method of measurement
ELISA.

Secondary outcomes

1

Description
IgG seroresponse rate against different serotypes after the booster dose: IgG seroresponse rate against different serotypes after the booster dose compared to the control group.
Timepoint
One month after the booster dose injection.
Method of measurement
ELISA. Percentage of individuals with IgG antibody concentration above 0.35 micrograms per milliliter.

2

Description
IgG GMC ratio against different serotypes after the booster dose: IgG GMC ratio against different serotypes after the booster dose in the candidate group compared to the control group.
Timepoint
One month after the booster dose injection.
Method of measurement
ELISA

3

Description
OPA seroresponse rate against different serotypes after 5 months and after the booster dose: OPA seroresponse rate against different serotypes after 5 months (one month after the third dose injection) and after the booster dose in the candidate group compared to the control group (in a subset of subjects).
Timepoint
One month after the third dose injection and one month after the booster dose injection.
Method of measurement
OPA. Percentage of individuals with functional antibody titer above 1:8

4

Description
OPA GMC ratio against different serotypes after 5 months and after the booster dose: OPA GMC ratio against different serotypes after 5 months (one month after the third dose injection) and after the booster dose in the candidate group compared to the control group (in a subset of subjects).
Timepoint
One month after the third dose injection and one month after the booster dose injection.
Method of measurement
OPA.

5

Description
Incidence of otitis media and pneumonia: Incidence of otitis media and pneumonia (specifying severity and pneumococcal strain type).
Timepoint
Throughout the study.
Method of measurement
Clinical examination and PCR.

6

Description
Number of individuals experiencing Immediate Adverse Drug Reactions within the first half-hour after each injection (Day 0).
Timepoint
In the first half-hour following each injection. (Day 0)
Method of measurement

Clinical assessment

7

Description

Number of individuals experiencing Solicited Adverse Drug Reactions in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

8

Description

Number of individuals experiencing Systematic Adverse Drug Reactions in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

9

Description

Number of individuals experiencing Unsolicited Adverse Drug Reactions in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

10

Description

Number of individuals experiencing Adverse Events of Special Interest (AESIs) in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection. AESIs include shoulder injury related to vaccine administration and vasovagal syncope.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

11

Description

Number of individuals experiencing Medically Attended Adverse Events (MAEs) in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection. MAEs include undesirable events demanding medical attendance that are not part of routine medical examination or vaccination visits, such as hospitalizations, emergency department visit, or any unscheduled medical visits for any reason.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

12

Description

Number of individuals experiencing Severe Adverse Events (SAEs) in the first 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection. SAEs refer to any adverse event resulting in death, life-threatening situations, need for hospitalization or prolongation of hospitalization, disability or congenital anomaly, and significant impairment of the participant under investigation.

Timepoint

First 7 days following each injection (Day 0-7), and then weekly until 1 month after the third dose injection and 1 month after the booster dose injection.

Method of measurement

Clinical assessment

Intervention groups

1

Description

Intervention group: PneumoConj®- manufactured by Nivad Pharmed Salamat The pre-filled syringe of 13-valent pneumococcal vaccine (PneumoConj®- manufactured by Nivad Pharmed Salamat), administered intramuscularly (right thigh muscle) at a dose of 0.5 milliliters at 2, 4, and 6 months of age in infants, with a booster dose administered at 12 to 15 months of age

Category

Prevention

2

Description

Control group: Prevnar®- manufactured by Pfizer The pre-filled syringe of 13-valent pneumococcal vaccine (Prevnar®- manufactured by Pfizer), administered intramuscularly (right thigh muscle) at a dose of 0.5 milliliters at 2, 4, and 6 months of age in infants, with a booster dose administered at 12 to 15 months of age

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Hakim Etemad Health Vaccination Center

Full name of responsible person
Dr.Eshaghi

Street address
Customs, Khosravi Kh., Majidzadeh Kh., Taimur Ebrahimi Kh., 71, Hakim Etemad Health Vaccination Center, Tehran, Iran

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Tehran

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Behdasht-Jonoob-Tehran@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
NivadPharmed Salamat company

Full name of responsible person
Dr. Mohammad Amin Ghobadi

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3164949682

Phone
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Email
a.ghobadi@nivadpharmed.com

Grant name

Grant code / Reference number

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

Title of funding source
NivadPharmed Salamat company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Orchid Pharmed Co.

Full name of responsible person
Dr. Hamidreza Kafi

Position
Medical Department Manager

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Province
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Postal code
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Phone
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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available