Clinical trial results:
A Phase 4, Randomized, Open-Label Trial to Describe The Safety, Tolerability, And Immunogenicity of 13-Valent Pneumococcal Conjugate Vaccine Formulated In Multidose Vials When Given With Routine Pediatric Vaccines in Healthy Infants in India

Summary

EudraCT number	2016-005134-29
Trial protocol	Outside EU/EEA
Global end of trial date	20 December 2019

Results information

Result version number	v1
This version publication date	25 June 2020
First version publication date	25 June 2020

Trial information

Trial identification

Sponsor protocol code	B4671004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03548337
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 February 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of 13-valent pneumococcal conjugate (13vPnC) with 2-phenoxyethanol (2-PE) in the multidose vial (MDV) group and without 2-PE in the single dose pre-filled syringe (PFS) group.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 December 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	India: 300
Worldwide total number of subjects	300
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	300
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 301 subjects were enrolled in the study. Out of 301 subjects, 300 were randomized and received the study vaccination.

Period 1

Period 1 title	Infant Series (duration of 3 months)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC: Multi-dose Vial (With Preservative)

Arm description:

Infant series: subjects were randomized to receive a single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) with preservative 2-phenoxyethanol (2-PE) from a multi-dose vial (MDV), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) diphtheria, tetanus, and pertussis; Haemophilus influenzae type b; and hepatitis B virus (DTP-Hib-HBV) vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine with preservative 2-PE from MDV, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	B467
Other name	13vPnC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of 13vPnC from a MDV with preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3).

Investigational medicinal product name	DTP-Hib-HBV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of DTP-Hib-HBV intramuscularly at age of 6 weeks, 10 weeks and 14 weeks.

Investigational medicinal product name	Rotavirus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of rotavirus vaccine intramuscularly at age of 6 weeks, 10 weeks and 14 weeks.

Arm title	13vPnC: Single-dose Prefilled Syringe (Without Preservative)

Arm description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC without preservative 2-PE from a single-dose prefilled syringe (PFS), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine without preservative 2-PE from single dose PFS, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Arm type	Active comparator
Investigational medicinal product name	13vPnC
Investigational medicinal product code	B467
Other name	13vPnC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of 13vPnC from single dose PFS without preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3).

Investigational medicinal product name	DTP-Hib-HBV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of DTP-Hib-HBV intramuscularly at age of 6 weeks, 10 weeks and 14 weeks.

Investigational medicinal product name	Rotavirus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of rotavirus vaccine intramuscularly at age of 6 weeks, 10 weeks and 14 weeks.

Number of subjects in period 1	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)
Started	150	150
Vaccination 1	150	150
Vaccination 2	144	144
Vaccination 3	144	141
Completed	139	139
Not completed	11	11
Adverse event, non-fatal	-	2
No Longer Met Eligibility Criteria	1	-
Lost to follow-up	2	1

Withdrawal by parent/guardian	8	8

Period 2

Period 2 title	Toddler dose (duration of 1 month)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	13vPnC: Multi-dose Vial (With Preservative)

Arm description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC from a MDV with preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) respectively along with 2 routine vaccines: 1) diphtheria, tetanus, and pertussis; Haemophilus influenzae type b; and hepatitis B virus (DTP- Hib-HBV) vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Toddler dose followed infant series. Toddler dose: subjects were administered a single 0.5 mL dose of 13vPnC vaccine from MDV with preservative 2-PE (Vaccination 4), at age of 12 months along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Arm type	Experimental
Investigational medicinal product name	13vPnC
Investigational medicinal product code	B467
Other name	13vPnC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of 13vPnC from a MDV with preservative 2-PE, intramuscularly at age of 12 months (Vaccination 4).

Investigational medicinal product name	Hepatitis A virus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of hepatitis A virus vaccine intramuscularly at age of 12 months.

Arm title	13vPnC: Single-dose Prefilled Syringe (Without Preservative)

Arm description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC from a single-dose PFS without preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) respectively along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Toddler dose followed infant series. Toddler dose: subjects were administered a single 0.5 mL dose of 13vPnC vaccine from single-dose PFS without preservative 2-PE (Vaccination 4), at age of 12 months along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Arm type	Active comparator
Investigational medicinal product name	13vPnC
Investigational medicinal product code	B467
Other name	13vPnC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of 13vPnC from single dose PFS without preservative 2-PE, intramuscularly at age of 12 months (Vaccination 4).

Investigational medicinal product name	Hepatitis A virus vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single 0.5 mL dose of hepatitis A virus vaccine intramuscularly at age of 12 months.

Number of subjects in period 2	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)
Started	139	139
Vaccination 4	139	139
Completed	138	138
Not completed	1	1
Withdrawal by parent/guardian	1	1

Baseline characteristics

Reporting groups

Reporting group title	13vPnC: Multi-dose Vial (With Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) with preservative 2-phenoxyethanol (2-PE) from a multi-dose vial (MDV), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) diphtheria, tetanus, and pertussis; Haemophilus influenzae type b; and hepatitis B virus (DTP-Hib-HBV) vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine with preservative 2-PE from MDV, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC: Single-dose Prefilled Syringe (Without Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC without preservative 2-PE from a single-dose prefilled syringe (PFS), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine without preservative 2-PE from single dose PFS, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)	Total
Number of subjects	150	150	300
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	150	150	300
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Weeks			
arithmetic mean	6.9	6.9	
standard deviation	± 0.95	± 0.99	-
Sex: Female, Male Units: Subjects			
Female	74	67	141
Male	76	83	159

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	150	150	300
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	0	0	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	150	150	300
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	13vPnC: Multi-dose Vial (With Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 milliliter (mL) dose of 13-valent pneumococcal conjugate vaccine (13vPnC) with preservative 2-phenoxyethanol (2-PE) from a multi-dose vial (MDV), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) diphtheria, tetanus, and pertussis; Haemophilus influenzae type b; and hepatitis B virus (DTP-Hib-HBV) vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine with preservative 2-PE from MDV, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC: Single-dose Prefilled Syringe (Without Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC without preservative 2-PE from a single-dose prefilled syringe (PFS), intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Infant series was followed by toddler dose. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine without preservative 2-PE from single dose PFS, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC: Multi-dose Vial (With Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC from a MDV with preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) respectively along with 2 routine vaccines: 1) diphtheria, tetanus, and pertussis; Haemophilus influenzae type b; and hepatitis B virus (DTP- Hib-HBV) vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Toddler dose followed infant series. Toddler dose: subjects were administered a single 0.5 mL dose of 13vPnC vaccine from MDV with preservative 2-PE (Vaccination 4), at age of 12 months along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC: Single-dose Prefilled Syringe (Without Preservative)

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC from a single-dose PFS without preservative 2-PE, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) respectively along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Toddler dose followed infant series. Toddler dose: subjects were administered a single 0.5 mL dose of 13vPnC vaccine from single-dose PFS without preservative 2-PE (Vaccination 4), at age of 12 months along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1[1]

End point description:

Local reactions were recorded daily using an daily electronic diary(e-diary). Local reactions included redness, swelling and pain at injection site. Redness and swelling were graded as mild (0.5 to 2.5 centimeters [cm]), moderate (2.5 to 7.0 cm) and, severe (greater than [>] 7 cm). Pain at injection site was graded as mild (hurts if gently touched (example, whimpers, winces, protests, or withdraws), moderate (hurts if gently touched [with crying]), and severe (causes limitation of limb movement). Subjects may be represented in more than 1 row. Here, "Any" for each of 3 local reactions represents

any grade of local reaction among mild, moderate or severe. Safety population for infant series included all subjects who received at least 1 dose of study vaccine during infant series. Here, "Overall Number of Subjects analyzed, N" signifies subjects who were evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	148		
Units: percentage of subjects				
number (confidence interval 95%)				
Redness: Any	19.7 (13.6 to 27.1)	16.9 (11.2 to 23.9)		
Redness: Mild	17.7 (11.9 to 24.8)	12.8 (7.9 to 19.3)		
Redness: Moderate	2.0 (0.4 to 5.8)	4.1 (1.5 to 8.6)		
Redness: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Swelling: Any	27.9 (20.8 to 35.9)	33.8 (26.2 to 42.0)		
Swelling: Mild	21.8 (15.4 to 29.3)	23.6 (17.1 to 31.3)		
Swelling: Moderate	6.1 (2.8 to 11.3)	10.1 (5.8 to 16.2)		
Swelling: Severe	0 (0.0 to 2.5)	0 (0.0 to 2.5)		
Pain at injection site: Any	61.9 (53.5 to 69.8)	67.6 (59.4 to 75.0)		
Pain at injection site: Mild	28.6 (21.4 to 36.6)	31.1 (25.6 to 41.3)		
Pain at injection site: Moderate	30.6 (23.3 to 38.7)	29.1 (21.9 to 37.1)		
Pain at injection site: Severe	2.7 (0.7 to 6.8)	5.4 (2.4 to 10.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events (SE) Within 7 Days After Vaccination 1

End point title	Percentage of Subjects With Systemic Events (SE) Within 7 Days After Vaccination 1[2]

End point description:

Systemic Events:recorded daily using an daily e-diary. Systemic events:Fever graded 1)less than(<)38.0 degrees Celsius[C],2)greater than or equal to(>=)38.0 degree C to 38.4 degree C,3)38.5 degree C to 38.9 degree C,4)39.0 degree C to 40.0 degree C,5)>40.0 degree C; Decreased appetite graded:mild(decreased interest in eating),moderate(decreased oral intake), severe(refusal to

graded:mild(increased or prolonged sleeping bouts),moderate(slightly subdued; interfering with daily activity),severe(disabling;not interested in usual daily activity); Irritability graded:mild(easily consolable),moderate(required increased attention),severe(inconsolable;crying could not be comforted). Subjects may be represented in >1 row."Any" for decreased appetite,increased sleep,irritability:any grade of these systemic events. Safety population for infant series:all subjects who received at least 1 dose of study vaccine during infant series. "N":subjects who were evaluable for this measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 1

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	148		
Units: percentage of subjects				
number (confidence interval 95%)				
Fever: <38.0 degree C	15.0 (9.6 to 21.8)	10.8 (6.3 to 17.0)		
Fever: >=38.0 degree C to 38.4 degree C	10.9 (6.4 to 17.1)	8.1 (4.3 to 13.7)		
Fever: 38.5 degree C to 38.9 degree C	1.4 (0.2 to 4.8)	2.7 (0.7 to 6.8)		
Fever: 39.0 degree C to 40.0 degree C	1.4 (0.2 to 4.8)	0 (0.0 to 2.5)		
Fever: >40.0 degree C	1.4 (0.2 to 4.8)	0 (0.0 to 2.5)		
Decreased appetite: Any	42.2 (34.1 to 50.6)	53.4 (45.0 to 61.6)		
Decreased appetite: Mild	23.8 (17.2 to 31.5)	30.4 (23.1 to 38.5)		
Decreased appetite: Moderate	17.7 (11.9 to 24.8)	21.6 (15.3 to 29.1)		
Decreased appetite: Severe	0.7 (0.0 to 3.7)	1.4 (0.2 to 4.8)		
Drowsiness: Any	55.1 (46.7 to 63.3)	66.2 (58.0 to 73.8)		
Drowsiness: Mild	29.3 (22.0 to 37.3)	33.1 (25.6 to 41.3)		
Drowsiness: Moderate	25.2 (18.4 to 33.0)	31.1 (23.7 to 39.2)		
Drowsiness: Severe	0.7 (0.0 to 3.7)	2.0 (0.4 to 5.8)		
Irritability: Any	64.6 (56.3 to 72.3)	65.5 (57.3 to 73.2)		
Irritability: Mild	37.4 (29.6 to 45.8)	32.4 (25.0 to 40.6)		
Irritability: Moderate	21.8 (15.4 to 29.3)	26.4 (19.5 to 34.2)		
Irritability: Severe	5.4 (2.4 to 10.4)	6.8 (3.3 to 12.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subejcts With Local Reactions Within 7 Days After Vaccination 2

End point title	Percentage of Subejcts With Local Reactions Within 7 Days After Vaccination 2[3]

End point description:

Local reactions were recorded daily using an electronic diary. Local reactions included redness, swelling and pain at injection site. Redness and swelling were graded as mild (0.5 to 2.5 cm), moderate (2.5 to 7.0 cm) and, severe (> 7 cm). Pain at injection site was graded as mild (hurts if gently touched (example, whimpers, winces, protests, or withdraws), moderate (hurts if gently touched [with crying]), and severe (causes limitation of limb movement). Subjects may be represented in more than 1 row. Here, "Any" for each of 3 local reactions represents any grade of local reaction among mild, moderate or severe. Safety population for infant series included all subjects who received at least 1 dose of study vaccine during infant series. Here, "N": number subjects who were evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 2

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	140		
Units: percentage of subjects				
number (confidence interval 95%)				
Redness: Any	17.0 (11.2 to 24.3)	19.3 (13.1 to 26.8)		
Redness: Mild	16.3 (10.6 to 23.5)	17.9 (11.9 to 25.2)		
Redness: Moderate	0.7 (0.0 to 3.9)	1.4 (0.2 to 5.1)		
Redness: Severe	0 (0.0 to 2.6)	0 (0.0 to 2.6)		
Swelling: Any	24.8 (17.9 to 32.8)	27.9 (20.6 to 36.1)		
Swelling: Mild	21.3 (14.8 to 29.0)	22.9 (16.2 to 30.7)		
Swelling: Moderate	3.5 (1.2 to 8.1)	5.0 (2.0 to 10.0)		
Swelling: Severe	0 (0.0 to 2.6)	0 (0.0 to 2.6)		
Pain at injection site: Any	59.6 (51.0 to 67.7)	62.1 (53.6 to 70.2)		
Pain at injection site: Mild	32.6 (25.0 to 41.0)	29.3 (21.9 to 37.6)		
Pain at injection site: Moderate	20.6 (14.2 to 28.2)	26.4 (19.3 to 34.5)		
Pain at injection site: Severe	6.4 (3.0 to 11.8)	6.4 (3.0 to 11.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2[4]

End point description:

Systemic Events:recorded daily using an daily e-diary. Systemic events:Fever graded 1)< 38.0 degrees C,2) >= 38.0 degree C to 38.4 degree C,3)38.5 degree C to 38.9 degree C,4)39.0 degree C to 40.0 degree C,5)>40.0 degree C; Decreased appetite graded: mild(decreased interest in eating),moderate(decreased oral intake), severe(refusal to feed);Drowsiness graded: mild(increased or prolonged sleeping bouts),moderate(slightly subdued; interfering with daily activity),severe (disabling;not interested in usual daily activity); Irritability graded: mild(easily consolable),moderate(required increased attention),severe(inconsolable;crying could not be comforted). Subjects may be represented in >1 row. "Any" for decreased appetite,increased sleep,irritability:any grade of these systemic events. Safety population for infant series:all subjects who received at least 1 dose of study vaccine during infant series. "N":subjects who were evaluable for this measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 2

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	140		
Units: percentage of subjects				
number (confidence interval 95%)				
Fever: <38.0 degree C	8.5 (4.5 to 14.4)	8.6 (4.5 to 14.5)		
Fever: >=38.0 degree C to 38.4 degree C	6.4 (3.0 to 11.8)	5.7 (2.5 to 10.9)		
Fever: 38.5 degree C to 38.9 degree C	2.1 (0.4 to 6.1)	2.1 (0.4 to 6.1)		
Fever: 39.0 degree C to 40.0 degree C	0 (0.0 to 2.6)	0 (0.0 to 2.6)		
Fever: >40.0 degree C	0 (0.0 to 2.6)	0.7 (0.0 to 3.9)		
Decreased appetite: Any	40.4 (32.3 to 49.0)	38.6 (30.5 to 47.2)		
Decreased appetite: Mild	27.0 (19.8 to 35.1)	25.0 (18.1 to 33.0)		
Decreased appetite: Moderate	12.1 (7.2 to 18.6)	12.1 (7.2 to 18.7)		
Decreased appetite: Severe	1.4 (0.2 to 5.0)	1.4 (0.2 to 5.1)		
Drowsiness: Any	50.4 (41.8 to 58.9)	52.1 (43.5 to 60.7)		
Drowsiness: Mild	23.4 (16.7 to 31.3)	22.1 (15.6 to 29.9)		
Drowsiness: Moderate	25.5 (18.6 to 33.6)	26.4 (19.3 to 34.5)		
Drowsiness: Severe	1.4 (0.2 to 5.0)	3.6 (1.2 to 8.1)		

Irritability: Any	56.7 (48.1 to 65.0)	60.0 (51.4 to 68.2)		
Irritability: Mild	29.1 (21.7 to 37.3)	37.9 (29.8 to 46.4)		
Irritability: Moderate	24.8 (17.9 to 32.8)	17.9 (11.9 to 25.2)		
Irritability: Severe	2.8 (0.8 to 7.1)	4.3 (1.6 to 9.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 3

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 3[5]

End point description:

Local reactions were recorded daily using an electronic diary. Local reactions included redness, swelling and pain at injection site. Redness and swelling were graded as mild (0.5 to 2.5 cm), moderate (2.5 to 7.0 cm) and, severe (> 7 cm). Pain at injection site was graded as mild (hurts if gently touched (example, whimpers, winces, protests, or withdraws), moderate (hurts if gently touched [with crying]), and severe (causes limitation of limb movement). Subjects may be represented in more than 1 row. Here, "Any" for each of 3 local reactions represents any grade of local reaction among mild, moderate or severe. Safety population for infant series included all subjects who received at least 1 dose of study vaccine during infant series. Here, "N": number subjects who were evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 3

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	140		
Units: percentage of subjects				
number (confidence interval 95%)				
Redness: Any	20.1 (13.8 to 27.8)	22.9 (16.2 to 30.7)		
Redness: Mild	20.1 (13.8 to 27.8)	20.0 (13.7 to 27.6)		
Redness: Moderate	0 (0.0 to 2.6)	2.9 (0.8 to 7.2)		
Redness: Severe	0 (0.0 to 2.6)	0 (0.0 to 2.6)		
Swelling: Any	23.0 (16.3 to 30.9)	27.1 (20.0 to 35.3)		
Swelling: Mild	20.9 (14.4 to 28.6)	23.6 (16.8 to 31.5)		
Swelling: Moderate	2.2 (0.4 to 6.2)	2.9 (0.8 to 7.2)		
Swelling: Severe	0 (0.0 to 2.6)	0.7 (0.0 to 3.9)		

Pain at injection site: Any	55.4 (46.7 to 63.8)	54.3 (45.7 to 62.7)		
Pain at injection site: Mild	30.2 (22.7 to 38.6)	27.9 (20.6 to 36.1)		
Pain at injection site: Moderate	23.0 (16.3 to 30.9)	21.4 (14.9 to 29.2)		
Pain at injection site: Severe	2.2 (0.4 to 6.2)	5.0 (2.0 to 10.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 3

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 3[6]

End point description:

Systemic Events:recorded daily using an daily e-diary. Systemic events:Fever graded 1)< 38.0 degrees C,2) >= 38.0 degree C to 38.4 degree C,3)38.5 degree C to 38.9 degree C,4)39.0 degree C to 40.0 degree C,5)>40.0 degree C; Decreased appetite graded: mild(decreased interest in eating),moderate(decreased oral intake), severe(refusal to feed);Drowsiness graded: mild(increased or prolonged sleeping bouts),moderate(slightly subdued; interfering with daily activity),severe (disabling;not interested in usual daily activity); Irritability graded: mild(easily consolable),moderate(required increased attention),severe(inconsolable;crying could not be comforted). Subjects may be represented in >1 row. "Any" for decreased appetite,increased sleep,irritability:any grade of these systemic events. Safety population for infant series:all subjects who received at least 1 dose of study vaccine during infant series. "N":subjects who were evaluable for this measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 3

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	140		
Units: percentage of subjects				
number (confidence interval 95%)				
Fever: <38.0 degree C	7.2 (3.5 to 12.8)	9.3 (5.0 to 15.4)		
Fever: >=38.0 degree C to 38.4 degree C	4.3 (1.6 to 9.2)	6.4 (3.0 to 11.9)		
Fever: 38.5 degree C to 38.9 degree C	2.2 (0.4 to 6.2)	1.4 (0.2 to 5.1)		
Fever: 39.0 degree C to 40.0 degree C	0 (0.0 to 2.6)	1.4 (0.2 to 5.1)		
Fever: >40.0 degree C	0.7 (0.0 to 3.9)	0 (0.0 to 2.6)		
Decreased appetite: Any	34.5 (26.7 to 43.1)	36.4 (28.5 to 45.0)		

Decreased appetite: Mild	20.0 (13.8 to 27.8)	23.6 (16.8 to 31.5)		
Decreased appetite: Moderate	11.5 (6.7 to 18.0)	10.0 (5.6 to 16.2)		
Decreased appetite: Severe	2.9 (0.8 to 7.2)	2.9 (0.8 to 7.2)		
Drowsiness: Any	36.0 (28.0 to 44.5)	39.3 (31.1 to 47.9)		
Drowsiness: Mild	20.9 (14.4 to 28.6)	19.3 (13.1 to 26.8)		
Drowsiness: Moderate	13.7 (8.4 to 20.5)	17.9 (11.9 to 25.2)		
Drowsiness: Severe	1.4 (0.2 to 5.1)	2.1 (0.4 to 6.1)		
Irritability: Any	54.7 (46.0 to 63.1)	60.0 (51.4 to 68.2)		
Irritability: Mild	31.7 (24.0 to 40.1)	37.9 (29.8 to 46.4)		
Irritability: Moderate	19.4 (13.2 to 27.0)	15.7 (10.1 to 22.8)		
Irritability: Severe	3.6 (1.2 to 8.2)	6.4 (3.0 to 11.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 4

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 4[7]

End point description:

Local reactions were recorded daily using an electronic diary. Local reactions included redness, swelling and pain at injection site. Redness and swelling were graded as mild (0.5 to 2.5 cm), moderate (2.5 to 7.0 cm) and, severe (> 7 cm). Pain at injection site was graded as mild (hurts if gently touched (example, whimpers, winces, protests, or withdraws), moderate (hurts if gently touched [with crying]), and severe (causes limitation of limb movement). Subjects may be represented in more than 1 row. Here, "Any" for each of 3 local reactions represents any grade of local reaction among mild, moderate or severe. Safety population for infant series included all subjects who received at least 1 dose of study vaccine during infant series. Here, "N": number subjects who were evaluable for this outcome measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 4

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	132		
Units: percentage of subjects				
number (confidence interval 95%)				

Redness: Any	8.3 (4.2 to 14.4)	11.4 (6.5 to 18.0)		
Redness: MIld	8.3 (4.2 to 14.4)	10.6 (5.9 to 17.2)		
Redness: Moderate	0 (0.0 to 2.8)	0.8 (0.0 to 4.1)		
Redness: Severe	0 (0.0 to 2.8)	0 (0.0 to 2.8)		
Swelling: Any	9.1 (4.8 to 15.3)	12.1 (7.1 to 18.9)		
Swelling: Mild	6.8 (3.2 to 12.5)	11.4 (6.5 to 18.0)		
Swelling: Moderate	2.3 (0.5 to 6.5)	0.8 (0.0 to 4.1)		
Swelling: Severe	0 (0.0 to 2.8)	0 (0.0 to 2.8)		
Pain at injection site: Any	25.0 (17.9 to 33.3)	19.7 (13.3 to 27.5)		
Pain at injection site: Mild	18.9 (12.6 to 26.7)	13.6 (8.3 to 20.7)		
Pain at injection site: Moderate	6.1 (2.7 to 11.6)	5.3 (2.2 to 10.6)		
Pain at injection site: Severe	0 (0.0 to 2.8)	0.8 (0.0 to 4.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 4

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 4[8]

End point description:

Systemic Events:recorded daily using an daily e-diary. Systemic events:Fever graded 1)< 38.0 degrees C,2) >= 38.0 degree C to 38.4 degree C,3)38.5 degree C to 38.9 degree C,4)39.0 degree C to 40.0 degree C,5)>40.0 degree C; Decreased appetite graded: mild(decreased interest in eating),moderate(decreased oral intake), severe(refusal to feed);Drowsiness graded: mild(increased or prolonged sleeping bouts),moderate(slightly subdued; interfering with daily activity),severe (disabling;not interested in usual daily activity); Irritability graded: mild(easily consolable),moderate(required increased attention),severe(inconsolable;crying could not be comforted). Subjects may be represented in >1 row. "Any" for decreased appetite,increased sleep,irritability:any grade of these systemic events. Safety population for infant series:all subjects who received at least 1 dose of study vaccine during infant series. "N":subjects who were evaluable for this measure.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 4

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	132		
Units: percentage of subjects				

number (confidence interval 95%)				
Fever: <38.0 degree C	3.0 (0.8 to 7.6)	4.5 (1.7 to 9.6)		
Fever: >=38.0 degree C to 38.4 degree C	1.5 (0.2 to 5.4)	3.8 (1.2 to 8.6)		
Fever: 38.5 degree C to 38.9 degree C	0 (0.0 to 2.8)	0 (0.0 to 2.8)		
Fever: 39.0 degree C to 40.0 degree C	0 (0.0 to 2.8)	0.8 (0.0 to 4.1)		
Fever: >40.0 degree C	1.5 (0.2 to 5.4)	0 (0.0 to 2.8)		
Decreased appetite: Any	15.2 (9.5 to 22.4)	16.7 (10.7 to 24.1)		
Decreased appetite: Mild	10.6 (5.9 to 17.2)	6.8 (3.2 to 12.5)		
Decreased appetite: Moderate	4.5 (1.7 to 9.6)	9.8 (5.3 to 16.3)		
Decreased appetite: Severe	0 (0.0 to 2.8)	0 (0.0 to 2.8)		
Drowsiness: Any	7.6 (3.7 to 13.5)	18.9 (12.6 to 26.7)		
Drowsiness: Mild	3.8 (1.2 to 8.6)	12.9 (7.7 to 19.8)		
Drowsiness: Moderate	3.8 (1.2 to 8.6)	6.1 (2.7 to 11.6)		
Drowsiness: Severe	0 (0.0 to 2.8)	0 (0.0 to 2.8)		
Irritability: Any	24.2 (17.2 to 32.5)	23.5 (16.5 to 31.6)		
Irritability: Mild	15.9 (10.1 to 23.3)	16.7 (10.7 to 24.1)		
Irritability: Moderate	7.6 (3.7 to 13.5)	5.3 (2.2 to 10.6)		
Irritability: Severe	0.8 (0.0 to 4.1)	1.5 (0.2 to 5.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) After Vaccination 1 up to 1 Month After Vaccination 3

End point title	Percentage of Subjects With Adverse Events (AEs) After Vaccination 1 up to 1 Month After Vaccination 3[9]

End point description:

An AE was any untoward medical occurrence in a subjects who received study vaccine without regard to possibility of causal relationship. Safety population for infant series included all subjects who received at least 1 dose of study vaccine during infant series.

End point type	Primary

End point timeframe:

First Vaccination 1 up to 1 Month after Vaccination 3 (for a maximum study duration of 3 months)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	150		
Units: percentage of subjects				
number (confidence interval 95%)	47.3 (39.1 to 55.6)	49.3 (41.1 to 57.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) From Vaccination 4 up to 1 Month After Vaccination 4

End point title	Percentage of Subjects With Adverse Events (AEs) From Vaccination 4 up to 1 Month After Vaccination 4[10]

End point description:

An AE was any untoward medical occurrence in a subjects who received study vaccine without regard to possibility of causal relationship. Safety population for toddler dose included all subjects who received at least 1 dose of study vaccine during toddler dosing.

End point type	Primary

End point timeframe:

From Vaccination 4 up to 1 month after Vaccination 4 (for a maximum study duration of 1 month)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	139		
Units: percentage of subjects				
number (confidence interval 95%)	7.9 (4.0 to 13.7)	8.6 (4.5 to 14.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Serious Adverse Events (SAEs) After Vaccination 1 up to 1 Month After Vaccination 4

End point title	Percentage of Subjects With Serious Adverse Events (SAEs) After Vaccination 1 up to 1 Month After Vaccination 4[11]

End point description:

An AE was any untoward medical occurrence in a subject who received study vaccine without regard to possibility of causal relationship. A SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Safety population for study included all subjects who received at least 1 dose of study vaccine in study.

End point type	Primary

End point timeframe:

From Vaccination 1 up to 1 month after Vaccination 4 (for a maximum study duration of 11.5 months)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	150		
Units: percentage of subjects				
number (confidence interval 95%)	8.0 (4.2 to 13.6)	4.7 (1.9 to 9.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With New Diagnosed Chronic Medical Condition (NDCMC) From 1 Month After Vaccination 3 up to Vaccination 4

End point title	Number of Subjects With New Diagnosed Chronic Medical Condition (NDCMC) From 1 Month After Vaccination 3 up to Vaccination 4[12]

End point description:

A newly diagnosed chronic medical condition was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Safety population for study included all subjects who received at least 1 dose of study vaccine in study.

End point type	Primary

End point timeframe:

From 1 month after Vaccination 3 up to Vaccination 4 (for a maximum study duration of 7.5 months)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was analyzed for this endpoint.

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	150		

Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immunoglobulin G (IgG) Concentrations Greater Than or Equal to (>=) Pre-defined Thresholds for Each of the Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point title	Percentage of Subjects With Immunoglobulin G (IgG) Concentrations Greater Than or Equal to (>=) Pre-defined Thresholds for Each of the Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point description:

Percentage of subjects achieving predefined antibody threshold: >=0.35 microgram per milliliter (mcg/mL) for the 10 pneumococcal serotypes 1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F and 23F; threshold >= 0.23 mcg/mL for serotype 5, threshold >= 0.10 mcg/mL for serotype 6B, threshold >= 0.12 mcg/mL for serotype 19A, along with the corresponding 95 percent (%) confidence interval (CI) are reported. Evaluable immunogenicity population for infant series: all eligible subjects aged 6 weeks at time of Dose 1, who received 3 doses of infant series vaccine, had blood drawn post-Dose 3 within 27 to 56 days (inclusive) post Dose 3, had at least 1 valid and determinate assay result post Dose 3, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after Vaccination 3

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	133		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype: 1	91.2 (85.1 to 95.4)	85.0 (77.7 to 90.6)		
Serotype: 3	91.9 (86.0 to 95.9)	85.7 (78.6 to 91.2)		
Serotype: 4	91.2 (85.1 to 95.4)	91.0 (84.8 to 95.3)		
Serotype: 5	84.6 (77.4 to 90.2)	82.0 (74.4 to 88.1)		
Serotype: 6A	83.8 (76.5 to 89.6)	71.4 (63.0 to 78.9)		
Serotype: 6B	77.2 (69.2 to 84.0)	75.2 (67.0 to 82.3)		
Serotype: 7F	96.3 (91.6 to 98.8)	93.2 (87.5 to 96.9)		

Serotype: 9V	85.3 (78.2 to 90.8)	83.5 (76.0 to 89.3)		
Serotype: 14	88.2 (81.6 to 93.1)	82.7 (75.2 to 88.7)		
Serotype: 18C	92.6 (86.9 to 96.4)	84.2 (76.9 to 90.0)		
Serotype: 19A	100.0 (97.3 to 100.0)	98.5 (94.7 to 99.8)		
Serotype: 19F	97.8 (93.7 to 99.5)	95.5 (90.4 to 98.3)		
Serotype: 23F	84.6 (77.4 to 90.2)	76.7 (68.6 to 83.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immunoglobulin G (IgG) Concentrations Greater Than or Equal to (>=) Pre-defined Thresholds for Each of the Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point title	Percentage of Subjects With Immunoglobulin G (IgG) Concentrations Greater Than or Equal to (>=) Pre-defined Thresholds for Each of the Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point description:

Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL for the 10 pneumococcal serotypes 1, 3, 4, 6A, 7F, 9V, 14, 18C, 19F and 23F, threshold >= 0.23 mcg/mL for serotype 5, threshold >= 0.10 mcg/mL for serotype 6B, threshold >= 0.12 mcg/mL for serotype 19A, along with the corresponding 95% CI are reported. Evaluable immunogenicity population for toddler dose: all eligible subjects who received 3 doses in infant series and 1 toddler dose of vaccine, had blood drawn post Dose 4 within 27 to 56 days, inclusive, post Dose 4, had at least 1 valid and determinate assay result post Dose 4, and had no major protocol violations. "Overall number of Subjects Analyzed": signifies number of subjects evaluable for this measure.

End point type	Secondary

End point timeframe:

1 month after Vaccination 4

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	129		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype: 1	99.2 (95.9 to 100.0)	100.0 (97.2 to 100.0)		
Serotype: 3	97.0 (92.4 to 99.2)	98.4 (94.5 to 99.8)		
Serotype: 4	99.2 (95.9 to 100.0)	100.0 (97.2 to 100.0)		

Serotype: 5	99.2 (95.9 to 100.0)	100.0 (97.2 to 100.0)		
Serotype: 6A	96.2 (91.4 to 98.8)	96.9 (92.3 to 99.1)		
Serotype: 6B	98.5 (94.6 to 99.8)	96.9 (92.3 to 99.1)		
Serotype: 7F	99.2 (95.9 to 100.0)	99.2 (95.8 to 100.0)		
Serotype: 9V	98.5 (94.6 to 99.8)	99.2 (95.8 to 100.0)		
Serotype: 14	97.7 (93.5 to 99.5)	96.1 (91.2 to 98.7)		
Serotype: 18C	97.0 (92.4 to 99.2)	99.2 (95.8 to 100.0)		
Serotype: 19A	99.2 (95.9 to 100.0)	99.2 (95.8 to 100.0)		
Serotype: 19F	98.5 (94.6 to 99.8)	100.0 (97.2 to 100.0)		
Serotype: 23F	99.2 (95.9 to 100.0)	96.9 (92.3 to 99.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point title	Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point description:

Antibody (IgG) GMC for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) and corresponding 2-sided 95% CI are reported. Evaluable immunogenicity population for infant series: all eligible subjects aged 6 weeks at time of Dose 1, who received 3 doses of infant series vaccine, had blood drawn post-Dose 3 within 27 to 56 days (inclusive) post Dose 3, had at least 1 valid and determinate assay result post Dose 3, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after Vaccination 3

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	133		
Units: mcg/mL				
geometric mean (confidence interval 95%)				
Serotype: 1	1.36 (1.15 to 1.60)	1.13 (0.94 to 1.36)		

Serotype: 3	1.01 (0.88 to 1.16)	0.93 (0.80 to 1.07)		
Serotype: 4	1.67 (1.40 to 1.98)	1.75 (1.45 to 2.11)		
Serotype: 5	0.83 (0.67 to 1.02)	0.86 (0.67 to 1.11)		
Serotype: 6A	1.45 (1.13 to 1.87)	0.86 (0.66 to 1.12)		
Serotype: 6B	0.41 (0.31 to 0.55)	0.33 (0.24 to 0.46)		
Serotype: 7F	2.01 (1.74 to 2.33)	1.85 (1.52 to 2.26)		
Serotype: 9V	1.42 (1.17 to 1.73)	1.28 (1.02 to 1.62)		
Serotype: 14	1.66 (1.33 to 2.06)	1.39 (1.09 to 1.76)		
Serotype: 18C	1.81 (1.50 to 2.18)	1.37 (1.10 to 1.71)		
Serotype: 19A	2.33 (1.96 to 2.78)	1.86 (1.51 to 2.28)		
Serotype: 19F	2.89 (2.52 to 3.31)	2.43 (2.04 to 2.89)		
Serotype: 23F	1.48 (1.20 to 1.81)	0.94 (0.73 to 1.21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point title	Immunoglobulin G (IgG) Geometric Mean Concentrations (GMCs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point description:

Antibody (IgG) GMC for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) and corresponding 2-sided 95% CI are reported. Evaluable immunogenicity population for toddler dose: all eligible subjects who received 3 doses in infant series and 1 toddler dose of vaccine, had blood drawn post-Dose 4 within 27 to 56 days (inclusive) post Dose 4, had at least 1 valid and determinate assay result post Dose 4, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after Vaccination 4

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: mcg/mL				
geometric mean (confidence interval				

95%)				
Serotype: 1	4.35 (3.71 to 5.10)	4.27 (3.65 to 4.99)		
Serotype: 3	1.58 (1.36 to 1.83)	1.63 (1.43 to 1.86)		
Serotype: 4	10.58 (8.89 to 12.60)	11.91 (10.19 to 13.93)		
Serotype: 5	5.16 (4.37 to 6.10)	5.68 (4.81 to 6.70)		
Serotype: 6A	18.55 (14.32 to 24.02)	20.51 (16.32 to 25.78)		
Serotype: 6B	11.76 (9.24 to 14.98)	10.87 (8.14 to 14.53)		
Serotype: 7F	7.92 (6.88 to 9.13)	8.29 (7.17 to 9.57)		
Serotype: 9V	8.78 (7.19 to 10.73)	9.57 (8.00 to 11.44)		
Serotype: 14	13.20 (10.69 to 16.30)	11.78 (9.31 to 14.90)		
Serotype: 18C	6.21 (5.19 to 7.44)	6.27 (5.25 to 7.48)		
Serotype: 19A	12.26 (10.26 to 14.65)	12.02 (9.75 to 14.82)		
Serotype: 19F	13.65 (11.16 to 16.69)	14.09 (11.71 to 16.96)		
Serotype: 23F	10.89 (8.78 to 13.50)	9.90 (7.75 to 12.66)		

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point title	Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMTs) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point description:

Antibody-mediated serum OPA against the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) was measured centrally using a pneumococcal OPA assay. Initial results were measured as OPA titers, which were then logarithmically transformed for analysis; geometric means calculated and expressed as GMTs. Evaluable immunogenicity population for infant series: all eligible subjects aged 6 weeks at time of Dose 1, who received 3 doses of infant series vaccine, had blood drawn post Dose 3 within 27 to 56 days (inclusive) post Dose 3, had at least 1 valid and determinate assay result post Dose 3, and had no major protocol violations.

End point type	Secondary

End point timeframe:

1 month after Vaccination 3

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	133		
Units: titer (1/dilution)				
geometric mean (confidence interval 95%)				
Serotype: 1	21.8 (18.1 to 26.2)	22.5 (18.1 to 27.9)		
Serotype: 3	79.7 (68.8 to 92.3)	72.8 (62.7 to 84.6)		
Serotype: 4	1158.8 (938.3 to 1431.1)	1159.2 (948.3 to 1417.0)		
Serotype: 5	37.0 (31.4 to 43.5)	40.9 (34.0 to 49.3)		
Serotype: 6A	1211.7 (896.4 to 1638.0)	1321.9 (1026.7 to 1701.9)		
Serotype: 6B	1145.8 (870.4 to 1508.3)	957.6 (708.2 to 1294.8)		
Serotype: 7F	1743.3 (1436.6 to 2115.5)	1178.8 (952.6 to 1458.6)		
Serotype: 9V	643.9 (498.6 to 831.7)	683.3 (522.6 to 893.3)		
Serotype: 14	496.9 (344.2 to 717.3)	341.8 (236.0 to 495.0)		
Serotype: 18C	3055.8 (2378.5 to 3926.0)	2183.9 (1686.9 to 2827.3)		
Serotype: 19A	219.3 (169.4 to 283.9)	275.7 (212.0 to 358.6)		
Serotype: 19F	236.1 (191.6 to 291.1)	272.7 (219.1 to 339.4)		
Serotype: 23F	1036.4 (746.9 to 1438.0)	926.8 (673.9 to 1274.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point title	Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point description:

Antibody-mediated serum OPA against the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) was measured centrally using a pneumococcal OPA assay. Initial results were measured as OPA titers, which were then logarithmically transformed for analysis; geometric means calculated and expressed as GMTs. Evaluable immunogenicity population for toddler dose: all eligible subjects who received 3 doses in infant series and 1 toddler dose of vaccine, had blood drawn post Dose 4 within 27 to 56 days (inclusive) post Dose 4, had at least 1 valid and determinate assay result post Dose 4, and had no major protocol violations.

End point type	Secondary
End point timeframe:	
1 month after Vaccination 4	

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: titer (1/dilution)				
geometric mean (confidence interval 95%)				
Serotype: 1	204.2 (164.7 to 253.3)	217.0 (176.4 to 266.9)		
Serotype: 3	121.0 (104.4 to 140.3)	129.8 (111.7 to 150.8)		
Serotype: 4	2991.4 (2437.5 to 3671.3)	2519.0 (2098.7 to 3023.6)		
Serotype: 5	157.6 (131.9 to 188.3)	153.4 (126.6 to 185.8)		
Serotype: 6A	2945.7 (2376.0 to 3652.1)	3092.5 (2493.5 to 3835.4)		
Serotype: 6B	1948.9 (1521.4 to 2496.7)	1750.1 (1360.9 to 2250.8)		
Serotype: 7F	4161.5 (3498.0 to 4950.9)	4353.8 (3706.5 to 5114.0)		
Serotype: 9V	6927.5 (5765.9 to 8323.2)	6460.4 (5277.3 to 7908.7)		
Serotype: 14	1505.8 (1246.5 to 1819.0)	1302.2 (1106.1 to 1533.2)		
Serotype: 18C	8028.3 (6233.7 to 10339.7)	7830.0 (5998.5 to 10220.7)		
Serotype: 19A	1848.9 (1472.0 to 2322.2)	1832.5 (1454.9 to 2308.1)		
Serotype: 19F	808.0 (633.0 to 1033.5)	766.0 (609.2 to 963.2)		
Serotype: 23F	3125.0 (2450.8 to 3984.7)	3348.8 (2639.5 to 4248.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >= Lower Limit of Quantitation (LLOQ) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point title	Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >= Lower Limit of Quantitation (LLOQ) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 3

End point description:

Percentage of subjects achieving OPA titer >=LLOQ along with 95% CI for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) determined in blood samples of subjects was presented. LLOQ (measured in mcg/mL) for each serotype is as follows: Seotype 1=18; Serotype 3=12; Serotype 4=21; Serotype 5=29; Serotype 6A=37; Serotype 6B=43; Serotype 7F=113; Serotype 9V=141; Serotype 14=35; Serotype 18C=31; Serotype 19A=18; Serotype 19F=48; Serotype 23F=13. Evaluable immunogenicity population for infant series: all eligible subjects aged 6 weeks at time of Dose 1, who received 3 doses of vaccine, had blood drawn post-Dose 3 within 27 to 56 days (inclusive) post Dose 3, had at least 1 valid and determinate assay result post Dose 3, and had no major protocol violations. "Overall Number of Subjects Analyzed": signifies number of subjects evaluable for this measure. "Number Analyzed, n": signifies subjects evaluable for specific serotype.

End point type	Secondary

End point timeframe:

1 month after Vaccination 3

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	108		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype: 1 (n=111, 106)	51.4 (41.7 to 61.0)	46.2 (36.5 to 56.2)		
Serotype: 3 (n=109, 107)	98.2 (93.5 to 99.8)	98.1 (93.4 to 99.8)		
Serotype: 4 (n=105, 101)	98.1 (93.3 to 99.8)	99.0 (94.6 to 100.0)		
Serotype: 5 (n=114, 107)	62.3 (52.7 to 71.2)	62.6 (52.7 to 71.8)		
Serotype: 6A (n= 113, 107)	91.2 (84.3 to 95.7)	94.4 (88.2 to 97.9)		
Serotype: 6B (n=109, 104)	94.5 (88.4 to 98.0)	92.3 (85.4 to 96.6)		
Serotype: 7F (n=96, 93)	99.0 (94.3 to 100.0)	96.8 (90.9 to 99.3)		
Serotype: 9V (n=103, 100)	88.3 (80.5 to 93.8)	88.0 (80.0 to 93.6)		
Serotype: 14 (n= 111, 108)	82.9 (74.6 to 89.4)	76.9 (67.8 to 84.4)		
Serotype: 18C (n=103, 99)	98.1 (93.2 to 99.8)	98.0 (92.9 to 99.8)		
Serotype: 19A (n= 101, 92)	92.1 (85.0 to 96.5)	95.7 (89.2 to 98.8)		
Serotype: 19F (n=107, 105)	89.7 (82.3 to 94.8)	91.4 (84.4 to 96.0)		
Serotype: 23F (n= 99, 98)	94.9 (88.6 to 98.3)	94.9 (88.5 to 98.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >= Lower Limit of Quantitation (LLOQ) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point title	Percentage of Subjects With Opsonophagocytic Activity (OPA) Titers >= Lower Limit of Quantitation (LLOQ) for Each of Pneumococcal Serotypes Measured 1 Month After Vaccination 4

End point description:

Percentage of subjects achieving OPA titer >=LLOQ along with 95% CI for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) determined in blood samples of subjects was presented. LLOQ (measured in mcg/mL) for each serotype is as follows: Seotype 1=18; Serotype 3=12; Serotype 4=21; Serotype 5=29; Serotype 6A=37; Serotype 6B=43; Serotype 7F=113; Serotype 9V=141; Serotype 14=35; Serotype 18C=31; Serotype 19A=18; Serotype 19F=48; Serotype 23F=13. Evaluable immunogenicity population for toddler dose: all eligible subejcts who received 3 doses in infant series and 1 toddler dose of vaccine, had blood drawn post Dose 4 within 27 to 56 days (inclusive) post Dose 4, had at least 1 valid and determinate assay result post Dose 4, and had no major protocol violations."Overall Number of Subjects Analyzed": signifies number of subjects evaluable for this measure. "Number Analyzed, n": signifies subjects evaluable for specific serotype.

End point type	Secondary

End point timeframe:

1 month after Vaccination 4

End point values	13vPnC: Multi-dose Vial (With Preservative)	13vPnC: Single-dose Prefilled Syringe (Without Preservative)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	106	102		
Units: percentage of subjects				
number (confidence interval 95%)				
Serotype: 1 (n=105, 102)	97.1 (91.9 to 99.4)	97.1 (91.6 to 99.4)		
Serotype: 3 (n=106, 101)	98.1 (93.4 to 99.8)	100.0 (96.4 to 100.0)		
Serotype: 4 (n=102, 99)	100.0 (96.4 to 100.0)	100.0 (96.3 to 100.0)		
Serotype: 5 (n=105, 102)	95.2 (89.2 to 98.4)	97.1 (91.6 to 99.4)		
Serotype: 6A (n=104, 101)	100.0 (96.5 to 100.0)	99.0 (94.6 to 100.0)		
Serotype: 6B (n=101, 101)	97.0 (91.6 to 99.4)	95.0 (88.8 to 98.4)		
Serotype: 7F (n=97, 90)	100.0 (96.3 to 100.0)	100.0 (96.0 to 100.0)		

Serotype: 9V (n=100, 98)	100.0 (96.4 to 100.0)	99.0 (94.4 to 100.0)		
Serotype: 14 (n=106, 101)	100.0 (96.6 to 100.0)	100.0 (96.4 to 100.0)		
Serotype: 18C (n=100, 100)	99.0 (94.6 to 100.0)	99.0 (94.6 to 100.0)		
Serotype: 19A (n=97, 96)	100.0 (96.3 to 100.0)	99.0 (94.3 to 100.0)		
Serotype: 19F (n=102, 99)	96.1 (90.3 to 98.9)	97.0 (91.4 to 99.4)		
Serotype: 23F (n=102, 96)	99.0 (94.7 to 100.0)	99.0 (94.3 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs= Infant series: 12 months post Vaccination 1; Toddler dose: 1 month post Vaccination 4, Non-SAEs=Infant series: 3 months post Vaccination 1; Toddler dose: 1 month post Vaccination 4, Local reactions and systemic events= 7 days post any vaccination

Adverse event reporting additional description:

An AE term may be reported as both a serious and non-serious AE, but are distinct events. An AE may be serious for 1 subject and non-serious for another subject or a subject may have experienced both a serious and non-serious episode of the same event. Safety population for infant series and toddler dose evaluated respectively.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	13vPnC, MDV With Preservative: Infant Series

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC with preservative 2-PE from a MDV, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC, PFS Without Preservative: Infant Series

Reporting group description:

Infant series: subjects were randomized to receive a single 0.5 mL dose of 13vPnC without preservative 2-PE from a single-dose PFS, intramuscularly at age of 6 weeks (Vaccination 1), 10 weeks (Vaccination 2) and 14 weeks (Vaccination 3) along with 2 routine vaccines: 1) DTP-Hib-HBV vaccine, 2) rotavirus vaccine. Subjects were followed-up to 1 month after Vaccination 3. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC, MDV With Preservative: Toddler Dose

Reporting group description:

Toddler dose followed infant series. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine with preservative 2-PE from MDV, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Reporting group title	13vPnC, PFS Without Preservative: Toddler Dose

Reporting group description:

Toddler dose followed infant series. Toddler dose: subjects were administered with a single 0.5 mL dose of 13vPnC vaccine without preservative 2-PE from single dose PFS, intramuscularly at age of 12 months (Vaccination 4) along with routine hepatitis A virus vaccine. Subjects were followed-up to 1 month after Vaccination 4. Different limbs were used to administer study vaccine and routine vaccines (according to local clinical practice).

Serious adverse events	13vPnC, MDV With Preservative: Infant Series	13vPnC, PFS Without Preservative: Infant Series	13vPnC, MDV With Preservative: Toddler Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 150 (3.33%)	4 / 150 (2.67%)	1 / 139 (0.72%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 150 (0.00%)	2 / 150 (1.33%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 139 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	4 / 150 (2.67%)	2 / 150 (1.33%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 150 (0.00%)	1 / 150 (0.67%)	0 / 139 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	1 / 139 (0.72%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	13vPnC, PFS Without Preservative: Toddler Dose		
Total subjects affected by serious			

adverse events			
subjects affected / exposed	0 / 139 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Nervous system disorders			
Seizure			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	13vPnC, MDV With Preservative: Infant Series	13vPnC, PFS Without Preservative: Infant Series	13vPnC, MDV With Preservative: Toddler Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	145 / 150 (96.67%)	141 / 150 (94.00%)	58 / 139 (41.73%)
Nervous system disorders			
Hypersomnia (Increased sleep)			
alternative assessment type: Systematic			
subjects affected / exposed	105 / 150 (70.00%)	116 / 150 (77.33%)	10 / 139 (7.19%)
occurrences (all)	228	274	10
General disorders and administration site conditions			
Injection site pain-1			
subjects affected / exposed	44 / 150 (29.33%)	46 / 150 (30.67%)	0 / 139 (0.00%)
occurrences (all)	103	111	0
Injection site pain-2			
alternative assessment type: Systematic			
subjects affected / exposed	117 / 150 (78.00%)	125 / 150 (83.33%)	33 / 139 (23.74%)
occurrences (all)	261	291	33
Injection site swelling			
subjects affected / exposed	17 / 150 (11.33%)	16 / 150 (10.67%)	0 / 139 (0.00%)
occurrences (all)	22	20	0
Pyrexia-1			
subjects affected / exposed	12 / 150 (8.00%)	7 / 150 (4.67%)	0 / 139 (0.00%)
occurrences (all)	15	12	0
Pyrexia- 2			
alternative assessment type: Systematic			
subjects affected / exposed	37 / 150 (24.67%)	32 / 150 (21.33%)	0 / 139 (0.00%)
occurrences (all)	45	41	0
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	64 / 150 (42.67%)	70 / 150 (46.67%)	12 / 139 (8.63%)
occurrences (all)	116	149	12
Skin and subcutaneous tissue disorders			

Erythema (Redness) alternative assessment type: Systematic			
subjects affected / exposed	52 / 150 (34.67%)	49 / 150 (32.67%)	11 / 139 (7.91%)
occurrences (all)	92	96	11
Psychiatric disorders Irritability alternative assessment type: Systematic			
subjects affected / exposed	114 / 150 (76.00%)	117 / 150 (78.00%)	32 / 139 (23.02%)
occurrences (all)	293	315	36
Infections and infestations Upper respiratory tract infection			
subjects affected / exposed	16 / 150 (10.67%)	10 / 150 (6.67%)	0 / 139 (0.00%)
occurrences (all)	16	15	0
Metabolism and nutrition disorders Decreased appetite alternative assessment type: Systematic			
subjects affected / exposed	92 / 150 (61.33%)	107 / 150 (71.33%)	20 / 139 (14.39%)
occurrences (all)	186	213	24

Non-serious adverse events	13vPnC, PFS Without Preservative: Toddler Dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 139 (38.85%)		
Nervous system disorders Hypersomnia (Increased sleep) alternative assessment type: Systematic			
subjects affected / exposed	25 / 139 (17.99%)		
occurrences (all)	27		
General disorders and administration site conditions Injection site pain-1			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences (all)	0		
Injection site pain-2 alternative assessment type: Systematic			
subjects affected / exposed	26 / 139 (18.71%)		
occurrences (all)	27		
Injection site swelling			

subjects affected / exposed	0 / 139 (0.00%)		
occurrences (all)	0		
Pyrexia-1			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences (all)	0		
Pyrexia- 2			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences (all)	0		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 139 (11.51%)		
occurrences (all)	18		
Skin and subcutaneous tissue disorders			
Erythema (Redness)			
alternative assessment type: Systematic			
subjects affected / exposed	15 / 139 (10.79%)		
occurrences (all)	17		
Psychiatric disorders			
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	31 / 139 (22.30%)		
occurrences (all)	35		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 139 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 139 (15.83%)		
occurrences (all)	28		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported