Clinical trial results:
A phase IIIb, observer-blind, controlled study to assess the safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine or Prevenar when given as a booster dose between 12-18 months of age in children previously vaccinated in the primary study 10PN-PD-DIT-012 (107007) with either GSK Biologicals' 10-valent pneumococcal conjugate vaccine or Prevenar.

Summary

EudraCT number	2006-005891-41
Trial protocol	PL
Global end of trial date	07 October 2008

Results information

Result version number	v1
This version publication date	16 March 2016
First version publication date	17 June 2015

Trial information

Trial identification

Sponsor protocol code	109509

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00547248
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.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	09 February 2009
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 October 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that a booster dose of GSK Biologicals' 10-valent pneumococcal conjugate vaccine(10Pn-PD-DiT) is non-inferior to Prevenar(7Pn) when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines, in terms of post-immunization booster reactions with rectal fever > 39.0°C in children at 12 to 18 months of age.

Criteria for safety:
Non-inferiority will be demonstrated if one can rule out an increase, in terms of percentage of subjects with rectal fever >39.0°C (10Pn-PD-DiT group as compared to Prevenar group), above 5% + half the incidence in the control group (= the null hypothesis) as shown by an one-sided P-value < 2.5%.

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.
As with all injectable vaccines, Tritanrix™-HepB should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Tritanrix™-HepB should under no circumstances be administered intravenously.

Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	22 October 2007
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 383
Country: Number of subjects enrolled	Philippines: 373
Worldwide total number of subjects	756
EEA total number of subjects	383

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)	756
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:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Blinding implementation details:

The study was conducted in an observer-blind/double-blind fashion. Due to the different appearance of the 10Pn-PD-DiT and Prevenar vaccines, a different person than the one who administered the vaccines, performed the safety assessments in order to keep the study double-blind.
In addition, the Clinical Report and the Individual Data Listings of the primary vaccination study 10PN-PD-DIT-012 were not shared with the Investigator before the booster study was over.

Arms

Are arms mutually exclusive?	Yes
Arm title	10PnEPI Group

Arm description:

Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV/Hib and OPV vaccines at 12-18 months of age.

Arm type	Experimental
Investigational medicinal product name	Pneumococcal conjugate vaccine GSK1024850A
Investigational medicinal product code	
Other name	10Pn-PD-DiT vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 booster dose administered in the right thigh or deltoid at 12-18 months of age

Investigational medicinal product name	Tritanrix™-HepB
Investigational medicinal product code	
Other name	DTPw-HBV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose administered in the left thigh or deltoid at 12-18 months of age, recombined with Hiberix.

Investigational medicinal product name	Hiberix™
Investigational medicinal product code	
Other name	Hib vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Reconstituted with Tritanrix-HepB before injection, 1-dose administered in the left thigh or deltoid at 12-18 months of age.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV vaccine
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

1 dose at 12-18 months of age

Arm title	7PnEPI Group

Arm description:

Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 12-18 months of age.

Arm type	Experimental
Investigational medicinal product name	Prevenar™
Investigational medicinal product code	
Other name	7Pn vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 booster dose administered in the right thigh or deltoid at 12-18 months of age

Investigational medicinal product name	Tritanrix™-HepB
Investigational medicinal product code	
Other name	DTPw-HBV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose administered in the left thigh or deltoid at 12-18 months of age, recombined with Hiberix.

Investigational medicinal product name	Hiberix™
Investigational medicinal product code	
Other name	Hib vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Reconstituted with Tritanrix-HepB before injection, 1-dose administered in the left thigh or deltoid at 12-18 months of age.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV vaccine
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

1 dose at 12-18 months of age

Arm title	10Pn246 Group

Arm description:

Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 12-18 months of age

Arm type	Experimental
Investigational medicinal product name	Pneumococcal conjugate vaccine GSK1024850A
Investigational medicinal product code	
Other name	10Pn-PD-DiT vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:	
1 booster dose administered in the right thigh or deltoid at 12-18 months of age	
Investigational medicinal product name	Tritanrix™-HepB
Investigational medicinal product code	
Other name	DTPw-HBV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose administered in the left thigh or deltoid at 12-18 months of age, recombined with Hiberix.	
Investigational medicinal product name	Hiberix™
Investigational medicinal product code	
Other name	Hib vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Reconstituted with Tritanrix-HepB before injection, 1-dose administered in the left thigh or deltoid at 12-18 months of age.	
Investigational medicinal product name	Poliorix™
Investigational medicinal product code	
Other name	IPV vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose administered in the lower left thigh or deltoid at 12-18 months of age	
Arm title	7Pn246 Group
Arm description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 12-18 months of age.	
Arm type	Experimental
Investigational medicinal product name	Prevenar™
Investigational medicinal product code	
Other name	7Pn vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 booster dose administered in the right thigh or deltoid at 12-18 months of age	
Investigational medicinal product name	Tritanrix™-HepB
Investigational medicinal product code	
Other name	DTPw-HBV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose administered in the left thigh or deltoid at 12-18 months of age, recombined with Hiberix.	
Investigational medicinal product name	Hiberix™
Investigational medicinal product code	
Other name	Hib vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Reconstituted with Tritanrix-HepB before injection, 1-dose administered in the left thigh or deltoid at 12-18 months of age.	

Investigational medicinal product name	Poliorix™
Investigational medicinal product code	
Other name	IPV vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose administered in the lower left thigh or deltoid at 12-18 months of age

Number of subjects in period 1	10PnEPI Group	7PnEPI Group	10Pn246 Group
Started	280	93	285
Completed	280	93	275
Not completed	0	0	10
Consent withdrawn by subject	-	-	7
Protocol deviation	-	-	1
Migrated/moved from study area	-	-	2
Protocol deviation	-	-	-

Number of subjects in period 1	7Pn246 Group
Started	98
Completed	96
Not completed	2
Consent withdrawn by subject	1
Protocol deviation	-
Migrated/moved from study area	-
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	10PnEPI Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV/Hib and OPV vaccines at 12-18 months of age.	
Reporting group title	7PnEPI Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 12-18 months of age.	
Reporting group title	10Pn246 Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 12-18 months of age	
Reporting group title	7Pn246 Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 12-18 months of age.	

Reporting group values	10PnEPI Group	7PnEPI Group	10Pn246 Group
Number of subjects	280	93	285
Age categorical			
Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: months			
arithmetic mean	16.2	16.2	17.2
standard deviation	± 0.66	± 0.59	± 0.84
Gender categorical			
Units: Subjects			
Female	133	43	134
Male	147	50	151

Reporting group values	7Pn246 Group	Total	
Number of subjects	98	756	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	

Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: months			
arithmetic mean	17.2		
standard deviation	± 0.88	-	
Gender categorical			
Units: Subjects			
Female	43	353	
Male	55	403	

End points

End points reporting groups

Reporting group title	10PnEPI Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV/Hib and OPV vaccines at 12-18 months of age.	
Reporting group title	7PnEPI Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 12-18 months of age.	
Reporting group title	10Pn246 Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 12-18 months of age	
Reporting group title	7Pn246 Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 12-18 months of age.	
Subject analysis set title	10pn group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
10pn epi+ 10pn246	
Subject analysis set title	7pn group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
7pnepi +7pn246	

Primary: Number of subjects reporting rectal temperature above (>) 39.0 degree Celsius (°C)

End point title	Number of subjects reporting rectal temperature above (>) 39.0 degree Celsius (°C)
End point description:	
Fever was measured as rectal temperature. Assessment of occurrences of fever > 39.0 °C was performed after booster vaccination of 10Pn-PD-DiT or 7Pn vaccine.	
End point type	Primary
End point timeframe:	
Within 4-day (Days 0-3) after booster vaccination.	

End point values	10pn group	7pn group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	558	189		
Units: Subjects				
Fever > 39.0°C	64	20		

Statistical analyses

Statistical analysis title	Non-inferiority of 10Pnvs7Pn vaccine after Booster

Statistical analysis description:

to demonstrate that a booster dose of 10Pn-PD-DiT vaccine administered at 12-18 months of age after a primary vaccination (either at 6-10-14 weeks or at 2-4-6 months of age), is non-inferior to 7Pn in terms of the incidence of rectal fever >39.0°C, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines.Towards this, standardized asymptotic 95% confidence interval (CI) for the difference [10Pn minus 7Pn] in terms of percentages of subjects reporting rectal fever >39.0°C was computed.

Comparison groups	10pn group v 7pn group
Number of subjects included in analysis	747
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
P-value	> 0.001 [2]
Method	Philips' statistical test
Parameter estimate	Difference in percentage
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.82
upper limit	5.59

Notes:

[1] - Non-inferiority was demonstrated if the difference in terms of incidence of post-immunization febrile reactions (rectal temperature > 39.0°C) in 10Pn-PD-DiT vaccine minus 7Pn did not exceed the pre-defined clinically acceptable threshold of 5% + half the incidence in 7Pn.

[2] - Phillips' statistical test, an extension of Farrington and Manning's methods, allows the inferiority limit (i.e. the tolerated absolute difference) to vary with the underlying failures rates. Observed P-value < 0.001.

Secondary: Number of subjects with any and Grade 3 solicited local symptoms

End point title	Number of subjects with any and Grade 3 solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 pain was defined as crying when limb was moved/spontaneously painful. Grade 3 swelling/redness was defined as swelling/redness larger than (>) 30 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity.

End point type	Secondary

End point timeframe:

Within 4-day (Days 0-3) after booster vaccination

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	280	93	278	96
Units: Subjects				
Any Pain	203	66	248	77
Grade 3 Pain	40	20	117	39
Any Redness	107	37	197	66
Grade 3 Redness	8	3	35	11
Any Swelling	92	32	158	52
Grade 3 Swelling	21	9	34	8

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and Grade 3 solicited general symptoms

End point title	Number of subjects with any and Grade 3 solicited general symptoms

End point description:

Solicited general symptoms assessed include drowsiness, fever (defined as rectal temperature ≥ 38.0°C), irritability, and loss of appetite. Grade 3 drowsiness was defined as drowsiness which prevented normal everyday activities. Grade 3 fever was defined as fever (rectal temperature) above (>) 40.0 degree Celsius (°C). Grade 3 irritability was defined as crying that could not be comforted/preventing normal activity. Grade 3 loss of appetite was defined as the subject not eating at all. "Any" is defined as incidence of the specified symptom regardless of intensity or relationship to study

End point type	Secondary

End point timeframe:

Within 4-day (Days 0-3) after booster vaccination

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	280	93	278	96
Units: Subjects				
Any Drowsiness	90	32	190	66
Grade 3 Drowsiness	5	1	7	2
Any Fever	138	51	215	65
Grade 3 Fever	0	0	1	0
Any Irritability	173	64	243	79
Grade 3 Irritability	12	3	40	5
Any Loss of appetite	97	28	184	57
Grade 3 Loss of appetite	8	1	13	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" is defined an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination.

End point type	Secondary

End point timeframe:
Within 31-day (Days 0-30) after booster vaccination

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	280	93	285	98
Units: Subjects				
Any AE(s)	25	9	106	35

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)

End point description:

End point type	Secondary

End point timeframe:
Throughout the active phase of the study (Month 0 to Month 1)

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	280	93	285	98
Units: Subjects				
Any SAE(s)	2	0	5	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)

End point description:

End point type	Secondary

End point timeframe:
Throughout the entire study period starting from the beginning of the booster phase (Month 0) up to the end of the 6-month safety follow-up period.

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	280	93	285	98
Units: Subjects				
Any SAE(s)	6	1	14	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (≥) 0.20 microgram per milliliter (µg/mL)

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (≥) 0.20 microgram per milliliter (µg/mL)

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				
Anti-1, Pre-booster [N=136;42;128;40]	100	2	64	2
Anti-1, Post-booster [N=136;42;125;43]	136	3	125	2
Anti-4, Pre-booster [N=135;43;130;42]	113	25	78	23
Anti-4, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-5, Pre-booster [N=135;42;129;42]	118	7	98	3
Anti-5, Post-booster [N=136;43;125;43]	136	8	124	3
Anti-6B, Pre-booster [N=135;43;129;44]	113	24	90	27
Anti-6B, Post-booster [N=136;42;125;43]	134	42	122	41
Anti-7F, Pre-booster [N=135;43;130;42]	128	7	118	1
Anti-7F, Post-booster [N=136;43;125;43]	136	9	125	1
Anti-9V, Pre-booster [N=135;42;130;44]	132	40	116	42

Anti-9V, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-14, Pre-booster [N=134;43;130;43]	126	42	111	40
Anti-14, Post-booster [N=136;43;125;43]	135	43	125	43
Anti-18C, Pre-booster [N=135;43;130;44]	130	36	111	35
Anti-18C, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-19F, Pre-booster [N=135;43;130;44]	129	11	121	22
Anti-19F, Post-booster [N=136;43;125;43]	136	43	123	43
Anti-23F, Pre-booster [N=133;43;130;44]	123	32	89	40
Anti-23F, Post-booster [N=136;43;125;43]	135	42	123	42

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations

End point title	Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations

End point description:

Seropositivity status, defined as anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations ≥0.05 microgram per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1, Pre-booster [N=136;42;128;40]	0.35 (0.29 to 0.42)	0.03 (0.03 to 0.04)	0.19 (0.16 to 0.22)	0.04 (0.03 to 0.05)
Anti-1, Post-booster [N=136;42;125;43]	10.8 (9.22 to 12.66)	0.04 (0.03 to 0.05)	2.14 (1.8 to 2.55)	0.04 (0.03 to 0.05)
Anti-4, Pre-booster [N=135;43;130;42]	0.55 (0.45 to 0.67)	0.34 (0.25 to 0.45)	0.27 (0.22 to 0.33)	0.24 (0.19 to 0.3)
Anti-4, Post-booster [N=136;43;125;43]	13.16 (11.43 to 15.14)	11.84 (8.74 to 16.04)	4.21 (3.61 to 4.91)	6.86 (5.39 to 8.73)
Anti-5, Pre-booster [N=135;42;129;42]	0.55 (0.47 to 0.64)	0.06 (0.04 to 0.09)	0.4 (0.34 to 0.47)	0.04 (0.03 to 0.05)
Anti-5, Post-booster [N=136;43;125;43]	14.59 (12.53 to 16.99)	0.09 (0.06 to 0.13)	2.54 (2.11 to 3.06)	0.05 (0.04 to 0.06)

Anti-6B, Pre-booster [N=135;43;129;44]	0.66 (0.54 to 0.8)	0.38 (0.22 to 0.65)	0.34 (0.28 to 0.41)	0.34 (0.2 to 0.59)
Anti-6B, Post-booster [N=136;42;125;43]	7.02 (5.83 to 8.45)	9.08 (6.5 to 12.7)	2.31 (1.93 to 2.75)	6.28 (4.18 to 9.44)
Anti-7F, Pre-booster [N=135;43;130;42]	0.9 (0.77 to 1.04)	0.05 (0.03 to 0.07)	0.58 (0.51 to 0.67)	0.03 (0.03 to 0.04)
Anti-7F, Post-booster [N=136;43;125;43]	12.52 (11.09 to 14.13)	0.06 (0.04 to 0.1)	4.14 (3.61 to 4.74)	0.03 (0.03 to 0.04)
Anti-9V, Pre-booster [N=135;42;130;44]	1.16 (0.98 to 1.37)	0.77 (0.59 to 0.99)	0.59 (0.5 to 0.7)	0.58 (0.47 to 0.71)
Anti-9V, Post-booster [N=136;43;125;43]	14.42 (12.44 to 16.7)	20.31 (15.44 to 26.71)	4.63 (4 to 5.36)	13.6 (11.12 to 16.62)
Anti-14, Pre-booster [N=134;43;130;43]	1.32 (1.07 to 1.63)	1.83 (1.26 to 2.66)	0.84 (0.66 to 1.07)	1.04 (0.75 to 1.43)
Anti-14, Post-booster [N=136;43;125;43]	17.07 (14.12 to 20.64)	27.42 (20.96 to 35.86)	5.93 (4.97 to 7.09)	15.51 (12.14 to 19.82)
Anti-18C, Pre-booster [N=135;43;130;44]	1.43 (1.2 to 1.71)	0.42 (0.32 to 0.55)	0.63 (0.52 to 0.77)	0.4 (0.3 to 0.53)
Anti-18C, Post-booster [N=136;43;125;43]	39.59 (34.04 to 46.05)	12.07 (9.23 to 15.79)	10.49 (8.81 to 12.49)	9.92 (7.74 to 12.71)
Anti-19F, Pre-booster [N=135;43;130;44]	1.33 (1.08 to 1.64)	0.16 (0.1 to 0.26)	0.99 (0.81 to 1.22)	0.35 (0.2 to 0.61)
Anti-19F, Post-booster [N=136;43;125;43]	21.25 (18.07 to 24.98)	6.61 (4.9 to 8.92)	12.23 (9.89 to 15.13)	6.01 (4.75 to 7.6)
Anti-23F, Pre-booster [N=133;43;130;44]	0.94 (0.76 to 1.16)	0.41 (0.26 to 0.64)	0.33 (0.27 to 0.4)	0.62 (0.43 to 0.91)
Anti-23F, Post-booster [N=136;43;125;43]	13.47 (11.38 to 15.94)	14.78 (9.45 to 23.11)	3.16 (2.61 to 3.83)	10.77 (7.19 to 16.12)

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

End point title	Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

End point description:

Seropositivity status, defined as Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F >= 8

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	125	37
Units: Titers				
geometric mean (confidence interval 95%)				
OPA Anti-1, Pre-booster [N=134;43;122;37]	13.2 (10.2 to 16.9)	4.6 (3.9 to 5.4)	8.5 (7 to 10.5)	4.7 (3.8 to 5.8)

OPA Anti-1, Post-booster [N=134;43;120;37]	1571.6 (1210.7 to 2040)	4.9 (4.1 to 5.8)	161.4 (120.7 to 215.9)	5.4 (4 to 7.4)
OPA Anti-4, Pre-booster [N=127;42;114;33]	40.5 (27.6 to 59.2)	18.5 (10 to 34.2)	12.5 (8.9 to 17.4)	12.4 (6.7 to 22.8)
OPA Anti-4, Post-booster [N=134;43;119;35]	5035.8 (4214 to 6017.8)	4783.5 (3432 to 6667.2)	2498.7 (2103.3 to 2968.4)	4812.5 (3167.8 to 7311.3)
OPA Anti-5, Pre-booster [N=133;43;119;36]	19.8 (16 to 24.7)	4.2 (3.8 to 4.6)	10.9 (8.8 to 13.6)	4.5 (3.7 to 5.5)
OPA Anti-5, Post-booster [N=130;43;117;36]	1135.8 (928.5 to 1389.6)	4.9 (3.9 to 6)	149.1 (115.4 to 192.5)	4.3 (3.8 to 4.8)
OPA Anti-6B, Pre-booster [N=132;43;124;37]	97.8 (61.5 to 155.5)	56.6 (21.3 to 150.1)	9.9 (7.2 to 13.5)	23.3 (9.1 to 60.1)
OPA Anti-6B, Post-booster [N=136;43;120;35]	2896.8 (2247.5 to 3733.8)	9302.7 (7187.3 to 12040.8)	405.3 (267.4 to 614.3)	3547.1 (1500.7 to 8384.5)
OPA Anti-7F, Pre-booster [N=135;41;116;31]	2278.4 (1803.1 to 2879)	378.8 (136.9 to 1048)	796.3 (582.2 to 1089.1)	63.6 (21.3 to 190.1)
OPA Anti-7F, Post-booster [N=136;40;122;24]	12484 (10750.7 to 14496.8)	1407.7 (694.6 to 2852.9)	6436.1 (5507.6 to 7521)	90.6 (25.2 to 325.5)
OPA Anti-9V, Pre-booster [N=136;42;122;37]	788 (655.1 to 947.8)	666.8 (482.1 to 922.2)	380.2 (313.1 to 461.7)	247.5 (164.9 to 371.3)
OPA Anti-9V, Post-booster [N=134;42;121;35]	4842 (4122.7 to 5686.9)	7387.8 (5429.2 to 10052.9)	3499.9 (2950.8 to 4151.3)	6881.4 (4883.6 to 9696.4)
OPA Anti-14, Pre-booster [N=130;42;106;31]	298.4 (220.1 to 404.7)	337.2 (207 to 549.2)	179.6 (127.4 to 253.2)	236.6 (132.6 to 422.2)
OPA Anti-14, Post-booster [N=132;42;120;36]	3579.7 (2966.3 to 4319.9)	4097.3 (3019.2 to 5560.2)	1961.3 (1630 to 2359.8)	2939.5 (2022.3 to 4272.7)
OPA Anti-18C, Pre-booster [N=129;42;121;37]	19.8 (15.2 to 25.9)	4.5 (3.9 to 5.2)	7.8 (6.5 to 9.4)	4.5 (4 to 5.2)
OPA Anti-18C, Post-booster [N=134;43;115;36]	2417.2 (1989.9 to 2936.2)	966.5 (607.1 to 1538.6)	694 (532.9 to 903.7)	612.1 (338.4 to 1107)
OPA Anti-19F, Pre-booster [N=135;43;125;37]	58.6 (45.2 to 76)	7.3 (4.5 to 11.8)	33.3 (25.7 to 43.2)	11.1 (6 to 20.6)
OPA Anti-19F, Post-booster [N=136;42;122;37]	2016 (1609 to 2526)	473.2 (263.5 to 849.9)	1059.8 (808.2 to 1389.7)	471 (270 to 821.8)
OPA Anti-23F, Pre-booster [N=136;43;118;36]	948.9 (688.4 to 1308.2)	661.9 (312.5 to 1402)	301.8 (198.4 to 459)	790.6 (326.8 to 1912.6)
OPA Anti-23F, Post-booster [N=136;43;121;37]	7456.2 (6301.9 to 8822)	23177.9 (13235.9 to 40587.7)	3427.3 (2727.7 to 4306.3)	19943.3 (13473.1 to 29520.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations to protein D (Anti-PD)

End point title	Antibody concentrations to protein D (Anti-PD)

End point description:

Seropositivity status, defined as anti-PD antibody concentrations >=100 ELISA units per milliliter (EL.U/mL)

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	135	43	128	43
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD, Pre-booster [N=132;43;128;43]	573.1 (495.7 to 662.6)	136.8 (102 to 183.3)	526.8 (427.4 to 649.3)	73.8 (58.4 to 93.2)
Anti-PD, Post-booster [N=135;43;125;43]	4973.9 (4280.2 to 5780)	124.1 (92.8 to 166)	2769.6 (2308.5 to 3322.7)	91.6 (72 to 116.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A

End point title	Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A

End point description:

Seropositivity status, defined as anti-pneumococcal cross-reactive serotypes 6A and 19A antibody concentrations >=0.05 microgram per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A, Pre-booster [N=135;43;130;43]	0.46 (0.36 to 0.6)	0.24 (0.14 to 0.4)	0.12 (0.1 to 0.14)	0.13 (0.08 to 0.2)
Anti-6A, Post-booster [N=136;43;125;43]	4.07 (3.09 to 5.36)	4.57 (2.92 to 7.17)	0.84 (0.65 to 1.08)	2.54 (1.65 to 3.93)
Anti-19A, Pre-booster [N=134;43;130;44]	0.24 (0.19 to 0.3)	0.08 (0.05 to 0.12)	0.16 (0.12 to 0.2)	0.06 (0.04 to 0.08)
Anti-19A, Post-booster [N=136;43;125;43]	3.22 (2.46 to 4.21)	0.58 (0.37 to 0.91)	1.75 (1.27 to 2.43)	0.38 (0.25 to 0.58)

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity (OPA) against pneumococcal cross-reactive serotypes 6A and 19A

End point title	Opsonophagocytic activity (OPA) against pneumococcal cross-reactive serotypes 6A and 19A

End point description:

Seropositivity status, defined as Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A >=8

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	134	43	123	36
Units: Titers				
geometric mean (confidence interval 95%)				
OPA Anti-6A Pre-booster [N=117;39;108;32]	113.6 (73.6 to 175.4)	191.4 (89.7 to 408.2)	46.8 (30.8 to 71.1)	42.2 (19.3 to 92.1)
OPA Anti-6A Post-booster [N=133;43;109;32]	882.8 (665.9 to 1170.3)	2563.8 (1689.9 to 3889.4)	369.7 (258.5 to 528.8)	1394.5 (827.9 to 2348.9)
OPA Anti-19A Pre-booster [N=134;43;123;36]	5.3 (4.5 to 6.3)	5.1 (3.6 to 7.3)	5.3 (4.5 to 6.2)	4.4 (3.6 to 5.3)
OPA Anti-19A Post-booster [N=133;40;115;32]	89.3 (58.9 to 135.4)	8.7 (5.4 to 14.2)	70.7 (45.3 to 110.4)	20.3 (8.8 to 46.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations ≥ 0.05 µg/mL

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations ≥ 0.05 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				
Anti-1, Pre-booster [N=136;42;128;40]	135	7	122	8
Anti-1, Post-booster [N=136;42;125;43]	136	11	125	9
Anti-4, Pre-booster [N=135;43;130;42]	134	43	126	42
Anti-4, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-5, Pre-booster [N=135;42;129;42]	135	18	128	13
Anti-5, Post-booster [N=136;43;125;43]	136	31	125	20
Anti-6B, Pre-booster [N=135;43;129;44]	132	40	127	39
Anti-6B, Post-booster [N=136;42;125;43]	135	42	124	42
Anti-7F, Pre-booster [N=135;43;130;42]	135	13	130	8
Anti-7F, Post-booster [N=136;43;125;43]	136	17	125	11
Anti-9V, Pre-booster [N=135;42;130;44]	135	42	130	44
Anti-9V, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-14, Pre-booster [N=134;43;130;43]	134	42	130	43
Anti-14, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-18C, Pre-booster [N=135;43;130;44]	135	43	129	44
Anti-18C, Post-booster [N=136;43;125;43]	136	43	125	43
Anti-19F, Pre-booster [N=135;43;130;44]	134	37	129	43
Anti-19F, Post-booster [N=136;43;125;43]	136	43	124	43
Anti-23F, Pre-booster [N=133;43;130;44]	132	40	125	43
Anti-23F, Post-booster [N=136;43;125;43]	136	42	124	42

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F ≥ 8

End point title	Number of subjects with opsonophagocytic activity (OPA) titers

	against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F ≥ 8

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	125	37
Units: Subjects				
OPA Anti-1, Pre-booster [N=134;43;122;37]	61	3	45	3
OPA Anti-1, Post-booster [N=134;43;120;37]	134	5	114	5
OPA Anti-4, Pre-booster [N=127;42;114;33]	83	20	39	12
OPA Anti-4, Post-booster [N=134;43;119;35]	134	43	119	35
OPA Anti-5, Pre-booster [N=133;43;119;36]	94	1	56	2
OPA Anti-5, Post-booster [N=130;43;117;36]	130	4	114	1
OPA Anti-6B, Pre-booster [N=132;43;124;37]	93	21	34	14
OPA Anti-6B, Post-booster [N=136;43;120;35]	134	43	106	32
OPA Anti-7F, Pre-booster [N=135;41;116;31]	133	28	109	15
OPA Anti-7F, Post-booster [N=136;40;122;24]	136	36	122	13
OPA Anti-9V, Pre-booster [N=136;42;122;37]	135	42	121	36
OPA Anti-9V, Post-booster [N=134;42;121;35]	134	42	121	35
OPA Anti-14, Pre-booster [N=130;42;106;31]	119	39	93	29
OPA Anti-14, Post-booster [N=132;42;120;36]	132	42	120	36
OPA Anti-18C, Pre-booster [N=129;42;121;37]	84	3	42	4
OPA Anti-18C, Post-booster [N=134;43;115;36]	133	42	114	36
OPA Anti-19F, Pre-booster [N=135;43;125;37]	117	7	96	12
OPA Anti-19F, Post-booster [N=136;42;122;37]	135	39	118	36
OPA Anti-23F, Pre-booster [N=136;43;118;36]	130	37	99	30
OPA Anti-23F, Post-booster [N=136;43;121;37]	136	42	120	37

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A ≥ 0.05 µg/mL

End point title	Number of subjects with concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A ≥ 0.05 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				
Anti-6A, Pre-booster [N=135;43;130;43]	128	37	105	33
Anti-6A, Post-booster [N=136;43;125;43]	133	42	125	42
Anti-19A, Pre-booster [N=134;43;130;44]	124	25	105	27
Anti-19A, Post-booster [N=136;43;125;43]	135	42	119	42

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with opsonophagocytic activity (OPA) against pneumococcal cross-reactive serotypes 6A and 19A ≥ 8

End point title	Number of subjects with opsonophagocytic activity (OPA) against pneumococcal cross-reactive serotypes 6A and 19A ≥ 8

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	134	43	123	36
Units: Subjects				
OPA Anti-6A Pre-booster [N=117;39;108;32]	82	30	63	19
OPA Anti-6A Post-booster [N=133;43;109;32]	127	43	97	32
OPA Anti-19A Pre-booster [N=134;43;123;36]	14	2	11	1
OPA Anti-19A Post-booster [N=133;40;115;32]	92	11	74	12

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with antibody concentrations against protein D (Anti-PD) ≥ 100 ELISA units per milliliter (EL.U/mL).

End point title	Number of subjects with antibody concentrations against protein D (Anti-PD) ≥ 100 ELISA units per milliliter (EL.U/mL).

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster dose of 10Pn-PD-DiT or 7Pn vaccine

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	135	43	128	43
Units: Subjects				
Anti-PD, Pre-booster [N=132;43;128;43]	131	28	117	11
Anti-PD, Post-booster [N= 135;43;125;43]	135	23	125	19

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (Anti-DT) and anti-tetanus toxoids (Anti-TT) antibody concentrations

End point title	Anti-diphtheria (Anti-DT) and anti-tetanus toxoids (Anti-TT) antibody concentrations

End point description:

Seroprotection status, defined as anti-diphtheria toxoid or anti-tetanus toxoid antibody concentrations

>= 0.1 IU/mL

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-DT, Pre-booster [N=65;25;62;24]	0.258 (0.209 to 0.319)	0.17 (0.118 to 0.243)	0.188 (0.153 to 0.231)	0.126 (0.088 to 0.179)
Anti-DT, Post-booster [N=65;25;59;24]	7.829 (6.339 to 9.671)	4.768 (3.699 to 6.145)	8.463 (7.11 to 10.074)	4.876 (3.503 to 6.787)
Anti-TT, Pre-booster [N= 65;25;62;24]	0.735 (0.629 to 0.858)	0.455 (0.314 to 0.66)	0.568 (0.432 to 0.748)	0.525 (0.29 to 0.951)
Anti-TT, Post-booster [N= 65;25;59;24]	20.979 (18.359 to 23.972)	9.703 (8.173 to 11.518)	12.171 (9.772 to 15.16)	6.719 (4.598 to 9.819)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point title	Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point description:

Seroprotection status, defined as anti-PRP antibody concentrations ≥0.15 µg/mL and ≥1.0 µg/mL

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, Pre-booster [N=65;25;62;24]	5.335 (3.578 to 7.953)	6.433 (2.93 to 14.124)	1.03 (0.745 to 1.423)	0.894 (0.57 to 1.401)
Anti-PRP, Post-booster [N=65;25;59;24]	106.004 (79.937 to 140.572)	89.376 (55.131 to 144.891)	53.386 (34.817 to 81.858)	33.656 (19.464 to 58.198)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Bordetella pertussis (BPT) antibody concentrations

End point title	Anti-Bordetella pertussis (BPT) antibody concentrations

End point description:

Seropositivity status, defined as anti-BPT antibody concentrations ≥15 EL.U/mL

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT, Pre-booster [N=65;25;62;24]	12.88 (10.86 to 15.28)	12.46 (9.32 to 16.65)	9.54 (8.34 to 10.91)	10 (8.21 to 12.19)
Anti-BPT, Post-booster [N=65;25;59;24]	139.51 (123.26 to 157.89)	133.45 (110.33 to 161.4)	121.73 (103.16 to 143.64)	121.76 (91.81 to 161.47)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-hepatitis B surface antigen (HBs) antibody concentrations

End point title	Anti-hepatitis B surface antigen (HBs) antibody concentrations

End point description:

Seroprotection status, defined as anti-HBs antibody concentrations ≥10 mIU/mL.

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	21	64	19
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Pre-booster [N=69;21;64;19]	30 (21.1 to 42.8)	23.4 (11.5 to 47.7)	97.9 (77 to 124.5)	113 (55.1 to 231.7)
Anti-HBs, Post-booster [N=69;21;62;19]	1220.5 (790.6 to 1884)	1098.1 (358.4 to 3364.9)	4428.7 (2980.3 to 6581)	3188.6 (1171.7 to 8677.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 antibody titers

End point title	Anti-polio type 1, 2 and 3 antibody titers

End point description:

Seroprotection status, defined as anti-polio type 1, anti-polio type 2 and anti-polio type 3 antibody titers ≥8

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	21	64	20
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, Pre-booster [N=69;21;63;20]	329.1 (214.9 to 504.1)	269 (114.8 to 630.3)	46.5 (33.6 to 64.4)	51.1 (28.4 to 91.9)
Anti-Polio 1, Post-booster [N=69;21;63;19]	854.6 (573.5 to 1273.5)	426.9 (166.2 to 1096.7)	932.5 (770.5 to 1128.6)	727.3 (512.9 to 1059.9)
Anti-Polio 2, Pre-booster [N=69;21;64;20]	222.6 (171.8 to 288.3)	210.4 (115.4 to 383.6)	50.2 (36.9 to 68.2)	60.8 (33.4 to 110.8)
Anti-Polio 2, Post-booster [N=69;21;63;19]	716.9 (487.6 to 1054.1)	689.1 (304.8 to 1557.9)	1195.7 (977.8 to 1462.2)	1206.6 (737 to 1975.4)
Anti-Polio 3, Pre-booster [N=69;21;64;20]	102.2 (73.9 to 141.5)	38.4 (20.3 to 72.9)	51.8 (37.4 to 71.7)	71.1 (36.2 to 139.5)
Anti-Polio 3, Post-booster [N=69;21;63;19]	232.7 (159.6 to 339.4)	190.4 (78.2 to 463.6)	1464.2 (1128 to 1900.6)	1346.2 (857.6 to 2113.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-Bordetella pertussis (BPT) with concentrations ≥ 15 EL.U/mL

End point title	Number of subjects with Anti-Bordetella pertussis (BPT) with concentrations ≥ 15 EL.U/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-BPT, Pre-booster [N=65;25;62;24]	28	10	12	7
Anti-BPT, Post-booster [N=65;25;59;24]	65	25	59	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-diphtheria (Anti-DT) and anti-tetanus toxoids (Anti-TT) antibody concentrations ≥ 0.1 mili-international units per mililiter (mIU/mL)

End point title	Number of subjects with anti-diphtheria (Anti-DT) and anti-tetanus toxoids (Anti-TT) antibody concentrations ≥ 0.1 mili-international units per mililiter (mIU/mL)

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-DT, Pre-booster [N=65;25;62;24]	56	18	49	15
Anti-DT, Post-booster [N=65;25;59;24]	65	25	59	24
Anti-TT, Pre-booster [N= 65;25;62;24]	65	24	60	23
Anti-TT, Post-booster [N= 65;25;59;24]	65	25	58	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration ≥ 0.15 µg/mL

End point title	Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration ≥ 0.15 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-PRP, Pre-booster [N=65;25;62;24]	65	25	58	23
Anti-PRP, Post-booster [N=65;25;59;24]	65	25	59	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration ≥ 1.0 µg/mL

End point title	Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration ≥ 1.0 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-PRP, Pre-booster [N=65;25;62;24]	56	22	32	12
Anti-PRP, Post-booster [N=65;25;59;24]	65	25	57	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-hepatitis B surface antigen (HBs) antibody concentrations ≥ 10 mIU/mL

End point title	Number of subjects with anti-hepatitis B surface antigen (HBs) antibody concentrations ≥ 10 mIU/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	21	64	19
Units: Subjects				
Anti-HBs, Pre-booster [N=69;21;64;19]	53	13	63	19
Anti-HBs, Post-booster [N=69;21;62;19]	68	19	62	19

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers ≥ 8

End point title	Number of subjects with anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers ≥ 8

End point description:

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	21	64	20
Units: Subjects				
Anti-Polio 1, Pre-booster [N=69;21;63;20]	64	19	56	19
Anti-Polio 1, Post-booster [N=69;21;63;19]	68	19	63	19
Anti-Polio 2, Pre-booster [N=69;21;64;20]	69	21	59	19
Anti-Polio 2, Post-booster [N=69;21;63;19]	69	21	63	19
Anti-Polio 3, Pre-booster [N=69;21;64;20]	65	17	61	18
Anti-Polio 3, Post-booster [N=69;21;63;19]	66	20	63	19

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine response to Anti-Bordetella pertussis (BPT)

End point title	Number of subjects with vaccine response to Anti-Bordetella pertussis (BPT)

End point description:

Vaccine response for anti-BPT, defined as the appearance of antibodies (i.e. concentrations ≥ 15 EL.U/mL) in subjects seronegative at pre-vaccination (i.e. with concentrations < 15 EL.U/mL), or at least 2-fold increase of pre-vaccination antibody concentrations in those who were initially seropositive at pre-vaccination (i.e. with concentrations ≥ 15 EL.U/mL).

End point type	Secondary

End point timeframe:

Prior to and one month after the booster vaccination of DTPw-HBV/Hib + OPV or IPV

End point values	10PnEPI Group	7PnEPI Group	10Pn246 Group	7Pn246 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	15	48	16
Units: Subjects				
Anti-BPT, S- [N=37;15;48;16]	37	15	48	16
Anti-BPT, S+ [N=28;10;11;7]	27	8	11	7

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms during the 4-day and Unsolicited AEs during the 31-day after booster vaccination; SAEs: throughout the entire study period from the beginning of the booster phase up to the end of the 6-month safety follow-up period

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	10PnEPI Group
Reporting group description: -	
Reporting group title	7PnEPI Group
Reporting group description: -	
Reporting group title	10Pn246 Group
Reporting group description: -	
Reporting group title	7Pn246 Group

Reporting group description: -

Serious adverse events	10PnEPI Group	7PnEPI Group	10Pn246 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 280 (2.14%)	1 / 93 (1.08%)	14 / 285 (4.91%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 280 (0.00%)	1 / 93 (1.08%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatoblastoma			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Internal injury			
subjects affected / exposed	0 / 280 (0.00%)	1 / 93 (1.08%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Thermal burn			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	3 / 280 (1.07%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 3	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 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglobulinaemia			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis haemorrhagic			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 280 (0.00%)	1 / 93 (1.08%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	5 / 285 (1.75%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	3 / 285 (1.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	2 / 285 (0.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	3 / 285 (1.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis rotavirus			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	2 / 285 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	0 / 285 (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
Clostridium difficile colitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infestation			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	0 / 285 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotavirus infection			

subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	1 / 285 (0.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	0 / 285 (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
Wound			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	0 / 285 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 280 (0.36%)	0 / 93 (0.00%)	0 / 285 (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

Serious adverse events	7Pn246 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 98 (5.10%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Brain neoplasm			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatoblastoma			

subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Internal injury			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 98 (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	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglobulinaemia			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enterocolitis haemorrhagic			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	2 / 98 (2.04%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Pharyngitis			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebiasis			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clostridium difficile colitis			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infestation			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			

subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotavirus infection			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 98 (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 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 98 (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	10PnEPI Group	7PnEPI Group	10Pn246 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	203 / 280 (72.50%)	66 / 93 (70.97%)	248 / 285 (87.02%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			

subjects affected / exposed[1]	203 / 280 (72.50%)	66 / 93 (70.97%)	248 / 278 (89.21%)
occurrences (all)	203	66	248
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	107 / 280 (38.21%)	37 / 93 (39.78%)	197 / 278 (70.86%)
occurrences (all)	107	37	197
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	92 / 280 (32.86%)	32 / 93 (34.41%)	158 / 278 (56.83%)
occurrences (all)	92	32	158
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[4]	90 / 280 (32.14%)	32 / 93 (34.41%)	190 / 278 (68.35%)
occurrences (all)	90	32	190
Fever (Rectally)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	138 / 280 (49.29%)	51 / 93 (54.84%)	215 / 278 (77.34%)
occurrences (all)	138	51	215
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[6]	173 / 280 (61.79%)	64 / 93 (68.82%)	243 / 278 (87.41%)
occurrences (all)	173	64	243
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[7]	97 / 280 (34.64%)	28 / 93 (30.11%)	184 / 278 (66.19%)
occurrences (all)	97	28	184
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	6 / 280 (2.14%)	3 / 93 (3.23%)	10 / 285 (3.51%)
occurrences (all)	6	3	10
Nasopharyngitis			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	15 / 285 (5.26%)
occurrences (all)	0	0	15
Pharyngitis			

subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	5 / 285 (1.75%)
occurrences (all)	0	0	5
Rhinitis			
subjects affected / exposed	3 / 280 (1.07%)	2 / 93 (2.15%)	11 / 285 (3.86%)
occurrences (all)	3	2	11

Non-serious adverse events	7Pn246 Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 98 (80.61%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	77 / 96 (80.21%)		
occurrences (all)	77		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	66 / 96 (68.75%)		
occurrences (all)	66		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	52 / 96 (54.17%)		
occurrences (all)	52		
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[4]	66 / 96 (68.75%)		
occurrences (all)	66		
Fever (Rectally)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	65 / 96 (67.71%)		
occurrences (all)	65		
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[6]	79 / 96 (82.29%)		
occurrences (all)	79		
Loss of appetite			

alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	57 / 96 (59.38%) 57		
Infections and infestations Gastroenteritis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all) Rhinitis subjects affected / exposed occurrences (all)	 5 / 98 (5.10%) 5 5 / 98 (5.10%) 5 6 / 98 (6.12%) 6 5 / 98 (5.10%) 5		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis of the solicited symptom included only subjects with documented data.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 March 2008	The protocol was amended to plan for an interim analysis on final cleaned safety and reactogenicity data. This allowed providing to the authorities additional safety and reactogenicity data of a booster dose of GSK Biologicals' 10Pn-PD-DiT vaccine co-administered with a DTPw-combined vaccine.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported