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	v2 (current)
This version publication date	11 August 2022
First version publication date	17 June 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

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 Diphtheria-tetanus-whole cell pertussis-hepatitis B vaccine with a lyophilized Haemophilus influenzae type b tetanus conjugate vaccine (DTPw-HBV/Hib) and Polio Sabin (OPV) or Poliorix (IPV) vaccines, in terms of post-immunization booster reactions with rectal temperature greater than (>) 39.0 degrees Celsius (°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 temperature >39.0°C (10Pn-PD-DiT group as compared to Prevenar group), above 5 percent (%) + half the incidence in the control group (= the null hypothesis) as shown by an one-sided P-value lesser than (<) 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	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group

Arm description:

Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of Synflorix vaccine, co-administered with Tritanrix-HepB/ Hiberix and Polio Sabin 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	Prevenar + Tritanrix -HepB/ Hiberix + Polio Sabin Group

Arm description:

Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Polio Sabin vaccines at 12-18 months of age.

Arm type	Experimental
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	Pneumococcal conjugate 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	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group

Arm description:

Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of Synflorix vaccine co-administered with Tritanrix -HepB/Hiberix and Poliorix 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	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group

Arm description:

Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Poliorix vaccines at 12-18 months of age.

Arm type	Experimental
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	Pneumococcal conjugate 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	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix -HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Started	280	93	285
Completed	280	93	275
Not completed	0	0	10
Consent withdrawn by subject	-	-	7
Migrated/moved from study area	-	-	2
Protocol deviation	-	-	1

Number of subjects in period 1	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group
Started	98
Completed	96
Not completed	2
Consent withdrawn by subject	1
Migrated/moved from study area	-
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of Synflorix vaccine, co-administered with Tritanrix-HepB/ Hiberix and Polio Sabin vaccines at 12-18 months of age.	
Reporting group title	Prevenar + Tritanrix -HepB/ Hiberix + Polio Sabin Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Polio Sabin vaccines at 12-18 months of age.	
Reporting group title	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of Synflorix vaccine co-administered with Tritanrix -HepB/Hiberix and Poliorix vaccines at 12-18 months of age.	
Reporting group title	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Poliorix vaccines at 12-18 months of age.	

Reporting group values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix -HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Number of subjects	280	93	285
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)	280	93	285
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: 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	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group	Total	
Number of subjects	98	756	

Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	98	756	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: months			
arithmetic mean	17.2		
standard deviation	± 0.88	-	
Gender categorical Units: Subjects			
Female	43	353	
Male	55	403	

Subject analysis sets	
Subject analysis set title	Synflorix Pooled Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: 10pn epi+ 10pn246	
Subject analysis set title	Prevenar Pooled Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: 7pnepi +7pn246	

Reporting group values	Synflorix Pooled Group	Prevenar Pooled Group	
Number of subjects	558	189	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	558	189	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: months			
arithmetic mean			
standard deviation	±	±	

Gender categorical Units: Subjects			
Female Male			

End points

End points reporting groups

Reporting group title	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of Synflorix vaccine, co-administered with Tritanrix-HepB/ Hiberix and Polio Sabin vaccines at 12-18 months of age.	
Reporting group title	Prevenar + Tritanrix -HepB/ Hiberix + Polio Sabin Group
Reporting group description:	
Subjects in the Philippines, primary vaccinated at 6-10-14 weeks of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Polio Sabin vaccines at 12-18 months of age.	
Reporting group title	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of Synflorix vaccine co-administered with Tritanrix -HepB/Hiberix and Poliorix vaccines at 12-18 months of age.	
Reporting group title	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description:	
Subjects in Poland, primary vaccinated at 2-4-6 months of age, receiving booster dose of the Prevenar vaccine, co-administered with Tritanrix -HepB/Hiberix and Poliorix vaccines at 12-18 months of age.	
Subject analysis set title	Synflorix Pooled Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
10pn epi+ 10pn246	
Subject analysis set title	Prevenar Pooled Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
7pnepi +7pn246	

Primary: Number of subjects reporting rectal temperature > the cut-off

End point title	Number of subjects reporting rectal temperature > the cut-off
End point description:	
Fever was measured as rectal temperature. The cut-off was 39.0°C. Assessment of occurrences of fever > 39.0 (°C) was performed after booster vaccination with Synflorix or Prevenar vaccines. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with the symptom sheets filled in. For the purpose of the analysis, subjects were pooled into two groups, according to the booster vaccine they have received (Synflorix or Prevenar).	
End point type	Primary
End point timeframe:	
Within 4-day (Days 0-3) period after booster vaccination	

End point values	Synflorix Pooled Group	Prevenar Pooled 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
Comparison groups	Synflorix Pooled Group v Prevenar Pooled Group
Number of subjects included in analysis	747
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
P-value	< 0.001
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 Synflorix (10Pn) vaccine minus Prevenar (7Pn) did not exceed the pre-defined clinically acceptable threshold of 5% + half the incidence in 7Pn.

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 included pain, redness and swelling. Grade 3 pain was defined as crying when limb was moved/spontaneously painful. "Any" was defined as incidence of the specified symptom regardless of intensity. Grade 3 swelling/redness was defined as swelling/redness > 30 millimeters (mm).
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with the symptom sheet filled-in.

End point type	Secondary

End point timeframe:

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

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 greater than or equal to (>=) 38.0°C], irritability, and loss of appetite. "Any" was defined as incidence of the specified symptom regardless of intensity or relationship to study vaccination. Grade 3 drowsiness was defined as drowsiness which prevented normal everyday activities. Grade 3 fever was defined as fever (rectal temperature) > 40.0°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.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with the symptom sheet filled-in.

End point type	Secondary

End point timeframe:

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

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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" was defined an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

Within the 31-day (Days 0-30) period after booster vaccination

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/ incapacity.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

Throughout the active phase of the study (Month 0 to Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 SAEs

End point title	Number of subjects with SAEs

End point description:

The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

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	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 >= the cut-off

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >= the cut-off

End point description:

The cut-off was 0.20 microgram per milliliter (µg/mL).
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				
Anti-1, Month 0 [N=136;42;128;40]	100	2	64	2
Anti-1, Month 1 [N=136;42;125;43]	136	3	125	2
Anti-4, Month 0 [N=135;43;130;42]	113	25	78	23
Anti-4, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-5, Month 0 [N=135;42;129;42]	118	7	98	3
Anti-5, Month 1 [N=136;43;125;43]	136	8	124	3
Anti-6B, Month 0 [N=135;43;129;44]	113	24	90	27
Anti-6B, Month 1 [N=136;42;125;43]	134	42	122	41
Anti-7F, Month 0 [N=135;43;130;42]	128	7	118	1
Anti-7F, Month 1 [N=136;43;125;43]	136	9	125	1
Anti-9V, Month 0 [N=135;42;130;44]	132	40	116	42
Anti-9V, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-14, Month 0 [N=134;43;130;43]	126	42	111	40
Anti-14, Month 1 [N=136;43;125;43]	135	43	125	43
Anti-18C, Month 0 [N=135;43;130;44]	130	36	111	35
Anti-18C, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-19F, Month 0 [N=135;43;130;44]	129	11	121	22
Anti-19F, Month 1 [N=136;43;125;43]	136	43	123	43
Anti-23F, Month 0 [N=133;43;130;44]	123	32	89	40
Anti-23F, Month 1 [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 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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 (0.20 to 0.59)
Anti-6B, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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-9V, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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)
OPA Anti-7F, Month 1 [N=136;42;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)

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 enzyme-linked immunosorbent assay (ELISA) units per milliliter (EL.U/mL).
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available, This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 Month 0 [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 Month 1 [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 Month 0 [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 Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >= the cut-off

End point description:

The cut-off of the assay was 0.05 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				

Anti-1, Month 0 [N=136;42;128;40]	135	7	122	8
Anti-1, Month 1 [N=136;42;125;43]	136	11	125	9
Anti-4, Month 0 [N=135;43;130;42]	134	43	126	42
Anti-4, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-5, Month 0 [N=135;42;129;42]	135	18	128	13
Anti-5, Month 1 [N=136;43;125;43]	136	31	125	20
Anti-6B, Month 0 [N=135;43;129;44]	132	40	128	39
Anti-6B, Month 1 [N=136;42;125;43]	135	42	125	42
Anti-7F, Month 0 [N=135;43;130;42]	135	13	127	8
Anti-7F, Month 1 [N=136;43;125;43]	136	17	124	11
Anti-9V, Month 0 [N=135;42;130;44]	135	42	130	44
Anti-9V, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-14, Month 0 [N=134;43;130;43]	134	42	130	43
Anti-14, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-18C, Month 0 [N=135;43;130;44]	135	43	129	44
Anti-18C, Month 1 [N=136;43;125;43]	136	43	125	43
Anti-19F, Month 0 [N=135;43;130;44]	134	37	129	43
Anti-19F, Month 1 [N=136;43;125;43]	136	43	124	43
Anti-23F, Month 0 [N=133;43;130;44]	132	40	125	43
Anti-23F, Month 1 [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>= the cut-off

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>= the cut-off

End point description:

The cut-off for the assay was 8.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [N=134;43;122;37]	61	3	45	3

OPA Anti-1, Month 1 [N=134;43;120;37]	134	5	114	5
OPA Anti-4, Month 0 [N=127;42;114;33]	83	20	39	12
OPA Anti-4, Month 1 [N=134;43;119;35]	134	43	119	35
OPA Anti-5, Month 0 [N=133;43;119;36]	94	1	56	2
OPA Anti-5, Month 1 [N=130;43;117;36]	130	4	114	1
OPA Anti-6B, Month 0 [N=132;43;124;37]	93	21	34	14
OPA Anti-6B, Month 1 [N=136;43;120;35]	134	43	106	32
OPA Anti-7F, Month 0 [N=135;41;116;31]	133	28	109	15
OPA Anti-7F, Month 1 [N=136;40;122;24]	136	36	122	13
OPA Anti-9V, Month 0 [N=136;42;122;37]	135	42	121	36
OPA Anti-9V, Month 1 [N=134;42;121;35]	134	42	121	35
OPA Anti-14, Month 0 [N=130;42;106;31]	119	39	93	29
OPA Anti-14, Month 1 [N=132;42;120;36]	132	42	120	36
OPA Anti-18C, Month 0 [N=129;42;121;37]	84	3	42	4
OPA Anti-18C, Month 1 [N=134;43;115;36]	133	42	114	36
OPA Anti-19F, Month 0 [N=135;43;125;37]	117	7	96	12
OPA Anti-19F, Month 1 [N=136;42;122;37]	135	39	118	36
OPA Anti-23F, Month 0 [N=136;43;118;36]	130	37	99	30
OPA Anti-23F,Month 1 [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 >= the cut-off

End point title	Number of subjects with concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A >= the cut-off

End point description:

The cut-off for the assay was 0.05 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	136	43	130	44
Units: Subjects				
Anti-6A, Month 0 [N=135;43;130;43]	128	37	105	33
Anti-6A, Month 1 [N=136;43;125;43]	133	42	125	42
Anti-19A, Month 0 [N=134;43;130;44]	124	25	105	27
Anti-19A, Month 1 [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 >= the cut-off

End point title	Number of subjects with opsonophagocytic activity (OPA) against pneumococcal cross-reactive serotypes 6A and 19A >= the cut-off

End point description:

The cut-off for the assay was 8.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 Month 0 [N=117;39;108;32]	82	30	63	19
OPA Anti-6A Month 1 [N=133;43;109;32]	127	43	97	32
OPA Anti-19A Month 0 [N=134;43;123;36]	14	2	11	1
OPA Anti-19A Month 1 [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) >= the cut-off

End point title	Number of subjects with antibody concentrations against protein D (Anti-PD) >= the cut-off

End point description:

The cut-off for the assay was 100 ELISA units per milliliter (EL.U/mL).
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	135	43	128	43
Units: Subjects				
Anti-PD, Month 0 [N=132;43;128;43]	131	28	117	11
Anti-PD, Month 1 [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 international units per milliliter (IU/mL).
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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. The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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 milli international units per milliliter (mIU/mL).

The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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, Month 0 [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, Month 1 [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 BPT with concentrations >= the cut-off

End point title	Number of subjects with BPT with concentrations >= the cut-off

End point description:

The cut-off for the assay was 15 EL.U/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-BPT, Month 0 [N=65;25;62;24]	28	10	12	7
Anti-BPT, Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-diphtheria (Anti-DT) and anti-tetanus toxoids (Anti-TT) antibody concentrations >= the cut-off

End point description:

The cut-off for the assay was 0.1 milli-international units per milliliter (mIU/mL).
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-DT, Month 0 [N=65;25;62;24]	56	18	49	15
Anti-DT, Month 1 [N=65;25;59;24]	65	25	59	24
Anti-TT, Month 0 [N= 65;25;62;24]	65	24	60	23
Anti-TT, Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration >= the cut-off

End point description:

The cut-off for the assay was 0.15 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-PRP, Month 0 [N=65;25;62;24]	65	25	58	23
Anti-PRP, Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration >= the cut-off

End point description:

The cut-off for the assay was 1.0 µg/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for persistence, which included all subjects for whom assay results were available for antibodies against at least one study vaccine antigen component for the blood sampling taken before the administration of the study booster dose (pre-booster blood sampling).

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	65	25	62	24
Units: Subjects				
Anti-PRP, Month 0 [N=65;25;62;24]	56	22	32	12
Anti-PRP, Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-hepatitis B surface antigen (HBs) antibody concentrations >= the cut-off

End point description:

The cut-off for the assay was 10 mIU/mL.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	21	64	19
Units: Subjects				
Anti-HBs, Month 0 [N=69;21;64;19]	53	13	63	19
Anti-HBs, Month 1 [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 >= the cut-off

End point title	Number of subjects with anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers >= the cut-off

End point description:

The cut-off for the assay was 8.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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, Month 0 [N=69;21;63;20]	64	19	56	19

Anti-Polio 1, Month 1 [N=69;21;63;19]	68	19	63	19
Anti-Polio 2, Month 0 [N=69;21;64;20]	69	21	59	19
Anti-Polio 2, Month 1 [N=69;21;63;19]	69	21	63	19
Anti-Polio 3, Month 0 [N=69;21;64;20]	65	17	61	18
Anti-Polio 3, Month 1 [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 BPT

End point title	Number of subjects with vaccine response to BPT

End point description:

Vaccine response for anti-BPT, defined as the appearance of antibodies in subjects seronegative at pre-vaccination, or at least 2-fold increase of pre-vaccination antibody concentrations in those who were initially seropositive at pre-vaccination.
The analysis was performed on the According-To-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available. This included subjects for whom assay results were available for antibodies against at least one study vaccine antigen component after booster vaccination.

End point type	Secondary

End point timeframe:

One month after booster vaccination (Month 1)

End point values	Synflorix + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix - HepB/ Hiberix + Poliorix Group	Prevenar + Tritanrix - HepB/ Hiberix + Poliorix 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 Month 0 to Month 6.

Adverse event reporting additional description:

The solicited local and general symptoms were only collected for those subjects who filled in their symptom sheets.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Synflorix + Tritanrix -HepB/ Hiberix + Polio Sabin Group
Reporting group description: -	
Reporting group title	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group
Reporting group description: -	
Reporting group title	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description: -	
Reporting group title	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group
Reporting group description: -	

Serious adverse events	Synflorix + Tritanrix -HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix 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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			
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	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			
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 alternative assessment type: Non-systematic			

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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix 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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatoblastoma			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglobulinaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 98 (1.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
alternative assessment type: Non-systematic			
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 98 (1.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Intussusception				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
subjects affected / exposed	2 / 98 (2.04%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia				

alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 98 (1.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 98 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 98 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amoebiasis				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 98 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infestation				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 98 (1.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nasopharyngitis				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
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				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 98 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
alternative assessment type: Non-systematic				
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 98 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound			
alternative assessment type: Non-systematic			
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			
alternative assessment type: Non-systematic			
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	Synflorix + Tritanrix -HepB/ Hiberix + Polio Sabin Group	Prevenar + Tritanrix - HepB/ Hiberix + Polio Sabin Group	Synflorix + Tritanrix -HepB/ Hiberix + Poliorix Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	237 / 280 (84.64%)	78 / 93 (83.87%)	276 / 285 (96.84%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed	203 / 280 (72.50%)	66 / 93 (70.97%)	248 / 285 (87.02%)
occurrences (all)	203	66	249
Erythema			
subjects affected / exposed	107 / 280 (38.21%)	37 / 93 (39.78%)	197 / 285 (69.12%)
occurrences (all)	107	37	197
Swelling			
subjects affected / exposed	92 / 280 (32.86%)	32 / 93 (34.41%)	158 / 285 (55.44%)
occurrences (all)	92	32	158
Somnolence			

subjects affected / exposed	90 / 280 (32.14%)	32 / 93 (34.41%)	190 / 285 (66.67%)
occurrences (all)	90	32	190
Fever (Rectally)			
subjects affected / exposed	138 / 280 (49.29%)	51 / 93 (54.84%)	215 / 285 (75.44%)
occurrences (all)	138	51	219
Irritability			
subjects affected / exposed	173 / 280 (61.79%)	64 / 93 (68.82%)	244 / 285 (85.61%)
occurrences (all)	173	64	244
Decreased appetite			
subjects affected / exposed	97 / 280 (34.64%)	28 / 93 (30.11%)	184 / 285 (64.56%)
occurrences (all)	97	28	184
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	14 / 285 (4.91%)
occurrences (all)	0	0	15
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 280 (0.00%)	0 / 93 (0.00%)	4 / 285 (1.40%)
occurrences (all)	0	0	4
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 280 (1.07%)	2 / 93 (2.15%)	11 / 285 (3.86%)
occurrences (all)	3	2	11

Non-serious adverse events	Prevenar + Tritanrix -HepB/ Hiberix + Poliorix Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 98 (93.88%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	77 / 98 (78.57%)		
occurrences (all)	77		
Erythema			
subjects affected / exposed	66 / 98 (67.35%)		
occurrences (all)	66		

Swelling			
subjects affected / exposed	52 / 98 (53.06%)		
occurrences (all)	52		
Somnolence			
subjects affected / exposed	66 / 98 (67.35%)		
occurrences (all)	66		
Fever (Rectally)			
subjects affected / exposed	65 / 98 (66.33%)		
occurrences (all)	65		
Irritability			
subjects affected / exposed	79 / 98 (80.61%)		
occurrences (all)	79		
Decreased appetite			
subjects affected / exposed	66 / 98 (67.35%)		
occurrences (all)	66		
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 98 (5.10%)		
occurrences (all)	5		
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 98 (6.12%)		
occurrences (all)	8		
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 98 (5.10%)		
occurrences (all)	5		

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