Clinical trial results:
A phase II, double-blind, multicentre study to evaluate the safety and immunogenicity of a booster dose of new formulations of GlaxoSmithKline Biologicals' combined DTPa-HBV-IPV/Hib vaccine in healthy toddlers, previously primed with three doses of the same vaccine in study 113948 (DTPA-HBV-IPV-124 PRI).

Summary

EudraCT number	2011-000876-33
Trial protocol	FI Outside EU/EEA
Global end of trial date	12 November 2012

Results information

Result version number	v3 (current)
This version publication date	06 September 2020
First version publication date	01 February 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	114843

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01453998
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 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	02 May 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 November 2012
Global end of trial reached?	Yes
Global end of trial date	12 November 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immunogenicity of at least one DTPa-HBV-IPV/Hib formulation is non-inferior to the licensed formulation in terms of seroprotection rates to diphtheria, tetanus, hepatitis B, poliovirus types 1, 2 and 3 and PRP antigens and in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens one month after the booster dose.

Protection of trial subjects:

As with all injectable vaccines, appropriate medical treatment was always readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee remained under medical supervision for 30 minutes after vaccination. DTPa vaccination was administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may have occured following an intramuscular administration to these subjects. DTPa vaccination was under no circumstances administered intravenously.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 October 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Dominican Republic: 248
Country: Number of subjects enrolled	Finland: 409
Worldwide total number of subjects	657
EEA total number of subjects	409

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)	657
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 272 subjects were enrolled in the study before the second protocol amendment and total of 385 after the amendment. After amendment 2, all subjects yet to receive a booster dose of a GSK217744 formulation, were administered the Infanrix hexa vaccine.

Period 1

Period 1 title	After Protocol Amendment 2.
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK217744 Group 1

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of either GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Arm title	GSK217744 Group 2

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of either GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Arm title	Infanrix hexa Group

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received

the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa™ in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Arm type	Active comparator
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Number of subjects in period 1[1]	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group
Started	131	130	124
Completed	130	130	124
Not completed	1	0	0
Consent withdrawn by subject	1	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 272 subjects were enrolled in the study before the second protocol amendment and total of 385 were enrolled after the amendment, hence the second period was the baseline.

Period 2

Period 2 title	Before Protocol Amendment 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK217744 Group 1

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of either GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

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

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Arm title	GSK217744 Group 2

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of either GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

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

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Arm title	Infanrix hexa Group

Arm description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa™ in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Arm type	Experimental
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose, licensed formulation, intramuscular into the right side of the thigh

Number of subjects in period 2[2]	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group
Started	85	88	99
Completed	85	88	99

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: A total of 272 subjects were enrolled in the study before the second protocol amendment and total of 385 were enrolled after the amendment, hence the second period was the baseline.

Baseline characteristics

Reporting groups	
Reporting group title	GSK217744 Group 1
Reporting group description:	
Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of either GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.	
Reporting group title	GSK217744 Group 2
Reporting group description:	
Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of either GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.	
Reporting group title	Infanrix hexa Group
Reporting group description:	
Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa™ in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.	

Reporting group values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group
Number of subjects	131	130	124
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)	131	130	124
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			
Baseline measure for subjects enrolled before protocol amendment 2.			
Units: Months			
arithmetic mean	14.1	13.9	14
standard deviation	± 0.6	± 0.6	± 0.6
Sex: Female, Male			
Baseline measure for subjects enrolled before protocol amendment 2.			
Units: Participants			
Female	61	76	53
Male	70	54	71

Reporting group values	Total		

Number of subjects	385		
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)	385		
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			
Baseline measure for subjects enrolled before protocol amendment 2.			
Units: Months			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Baseline measure for subjects enrolled before protocol amendment 2.			
Units: Participants			
Female	190		
Male	195		

End points

End points reporting groups

Reporting group title	GSK217744 Group 1

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of either GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 2

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of either GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa™ in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 1

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of either GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 2

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of either GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) or Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa™ in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Primary: Number of seroprotected subjects for anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies

End point title	Number of seroprotected subjects for anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies[1]

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-D and anti-T antibody concentrations ≥ 0.1 international units per milliliter (IU/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: Participants				
Anti-D, POST (N=81, 82, 90)	81	82	90	
Anti-T, POST (N=81, 82, 90)	81	82	90	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects for anti-diptheria and anti-T antibody

End point title	Number of seroprotected subjects for anti-diptheria and anti-T antibody[2]

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-D and anti-T antibody concentrations ≥ 0.1 international units per milliliter (IU/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	118	
Units: Participants				
Anti-D, POST (N=123, 122, 118)	123	122	118	
Anti-T, POST (N=123, 122, 118)	123	122	118	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-Hepatitis B (anti-HBs) antigens

End point title	Number of seroprotected subjects against anti-Hepatitis B (anti-HBs) antigens[3]

End point description:

A seroprotected subject was a subject whose antibody concentration was greater than or equal to the level defining clinical protection of 10 milli-international units per millilitre (mIU/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	79	84	
Units: Participants	78	78	84	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-HBs antigens

End point title	Number of seroprotected subjects against anti-HBs antigens[4]

End point description:

A seroprotected subject was a subject whose antibody concentration was greater than or equal to the level defining clinical protection of 10 milli-international units per millilitre (mIU/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	115	115	
Units: Participants	121	113	114	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects for anti-poliovirus types 1, 2 and 3

End point title	Number of Seroprotected Subjects for anti-poliovirus types 1, 2 and 3[5]

End point description:

A seroprotected subject was a subject whose antibody titre was greater than or equal to the level

defining clinical protection of 8.

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	85	
Units: Participants				
Anti-Polio 1, POST (N= 77, 72, 85)	76	72	85	
Anti-Polio 2, POST (N= 62, 61, 76)	62	60	76	
Anti-Polio 3, POST (N= 64, 63, 73)	64	63	71	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Seroprotected Subjects for anti-poliovirus (type 1, 2 and 3)

End point title	Number of Seroprotected Subjects for anti-poliovirus (type 1, 2 and 3)[6]

End point description:

A seroprotected subject was a subject whose antibody titre was greater than or equal to the level defining clinical protection of 8.

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	113	107	103	
Units: Participants				
Anti-Polio 1, POST (N= 111, 107, 103)	111	107	102	
Anti-Polio 2, POST (N= 96, 97, 87)	96	96	87	
Anti-Polio 3, POST (N= 113, 103, 98)	113	103	98	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects for anti-polyribosyl-ribitol phosphate (anti-PRP)

End point title	Number of seroprotected subjects for anti-polyribosyl-ribitol phosphate (anti-PRP)[7]

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: Participants	81	82	90	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects for anti-PRP

End point title	Number of seroprotected subjects for anti-PRP[8]

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL).

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	118	
Units: Participants				
Anti-PRP seroprotected subjects (N= 123, 122, 117)	122	122	117	

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin (anti-PRN)

End point title	Concentrations for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin (anti-PRN)[9]

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seropositivity cut-off assay was 5 EL.U/mL.

End point type	Primary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, POST (N= 79, 81, 89)	76.1 (66.1 to 87.6)	74.3 (62.6 to 88.1)	96.0 (83.5 to 110.3)	
Anti-FHA, POST (N= 81, 82, 90)	393.7 (346.4 to 447.6)	372.4 (332.7 to 416.7)	423.0 (368.1 to 485.9)	
Anti-PRN, POST (N= 81, 81, 89)	213.0 (178.1 to 254.7)	180.0 (154.2 to 210.1)	372.9 (309.3 to 449.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations for anti-PT, anti-FHA, anti-PRN

End point title	Concentrations for anti-PT, anti-FHA, anti-PRN[10]

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seropositivity cut-off assay was 5 EL.U/mL.

End point type	Primary

End point timeframe:

1 month post booster vaccination (subjects enrolled after protocol amendment 2)

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis not applicable for this endpoint

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	117	
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, POST (N= 118, 121, 116)	92.4 (80.6 to 106.0)	93.6 (83.1 to 105.5)	132.6 (114.9 to 153.0)	
Anti-FHA, POST (N=123, 122, 117)	467.3 (417.3 to 523.3)	446.2 (402.3 to 494.9)	582.9 (517.1 to 657.1)	
Anti-PRN, POST (N= 122, 122, 117)	253.2 (216.9 to 295.6)	181.0 (154.8 to 211.7)	401.1 (342.2 to 470.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies

End point title	Concentrations for anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.1 IU/mL.

End point type	Secondary

End point timeframe:

Before (PRE) and 1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, POST (N= 81, 82, 90)	5.652 (4.985 to 6.408)	5.494 (4.891 to 6.171)	6.772 (5.897 to 7.777)	
Anti-T, POST (N= 81, 82, 90)	5.015 (4.341 to 5.794)	5.034 (4.366 to 5.803)	5.571 (4.869 to 6.374)	
Anti-D, PRE (N= 81, 82, 89)	0.357 (0.305 to 0.419)	0.445 (0.381 to 0.520)	0.401 (0.343 to 0.468)	
Anti-T, PRE (N= 81, 82, 89)	0.358 (0.301 to 0.427)	0.362 (0.306 to 0.428)	0.394 (0.337 to 0.459)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-D and anti-T antibodies

End point title	Concentrations for anti-D and anti-T antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.1 IU/mL.

End point type	Secondary

End point timeframe:

Before (PRE) 1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	118	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, POST (N= 123, 122, 118)	6.327 (5.698 to 7.025)	5.452 (4.956 to 5.998)	7.192 (6.419 to 8.059)	
Anti-T, POST (N= 123, 122, 118)	5.986 (5.204 to 6.885)	5.316 (4.716 to 5.992)	5.993 (5.222 to 6.878)	
Anti-D, PRE (N= 123, 121, 117)	0.247 (0.213 to 0.287)	0.278 (0.244 to 0.317)	0.304 (0.258 to 0.360)	
Anti-T, PRE (N= 123, 121, 117)	0.364 (0.313 to 0.422)	0.332 (0.289 to 0.380)	0.331 (0.285 to 0.383)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-D and anti-T antibodies

End point title	Number of seroprotected subjects for anti-D and anti-T antibodies

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-D and anti-T antibody concentrations ≥ 0.1 international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: Participants				
Anti-D, PRE (N= 81, 82, 90)	78	80	84	
Anti-T, PRE (N= 81, 82, 90)	76	78	85	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-diptheria and anti-T antibodies

End point title	Number of seroprotected subjects for anti-diptheria and anti-T antibodies

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-D and anti-T antibody concentrations ≥ 0.1 international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	117	
Units: Participants				
Anti-D, PRE (N= 123, 121, 117)	107	114	104	
Anti-T, PRE (N= 123, 121, 117)	116	114	111	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin

End point title	Concentrations for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seropositivity cut-off assay was 5 EL.U/mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	89	
Units: EL.U/mL.				
geometric mean (confidence interval 95%)				
Anti-PT, PRE (N= 80, 80, 87)	10.5 (8.8 to 12.6)	9.5 (7.9 to 11.4)	12.7 (10.8 to 15.0)	
Anti-FHA, PRE (N= 81, 82, 88)	41.7 (35.4 to 49.2)	36.9 (31.5 to 43.3)	47.1 (40.3 to 55.1)	
Anti-PRN, PRE (N= 81, 81, 89)	12.8 (10.4 to 15.7)	10.8 (8.9 to 13.1)	18.2 (15.0 to 22.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PT, anti-FHA and anti-PRN

End point title	Concentrations for anti-PT, anti-FHA and anti-PRN

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seropositivity cut-off assay was 5 EL.U/mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	117	
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, PRE (N= 123, 121, 117)	8.3 (7.2 to 9.7)	7.9 (6.8 to 9.1)	9.9 (8.5 to 11.5)	
Anti-FHA, PRE (N= 123, 118, 116)	37.6 (32.5 to 43.4)	34.0 (28.7 to 40.4)	45.7 (38.8 to 53.9)	
Anti-PRN, PRE (N= 123, 121, 117)	11.6 (9.7 to 13.9)	9.7 (8.1 to 11.7)	15.6 (13.0 to 18.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA) and anti-Pertactin (anti-PRN)

End point title	Number of seropositive subjects for anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA) and anti-Pertactin (anti-PRN)

End point description:

A seropositive subject was a subject whose antibody concentration was greater than or equal to (≥) the assay cut-off of 5 ELISA units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: Participants				
Anti-PT, POST (N= 79, 81, 89)	79	81	89	
Anti-FHA, POST (N= 81, 82, 90)	81	82	90	
Anti-PRN, POST (N= 81, 81, 89)	81	81	89	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-PT, anti-FHA, anti-PRN

End point title	Number of seropositive subjects for anti-PT, anti-FHA, anti-PRN

End point description:

A seropositive subject was a subject whose antibody concentration was greater than or equal to (≥) the assay cut-off of 5 ELISA units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	117	
Units: Participants				
Anti-PT, POST (N= 118, 121, 116)	118	121	116	
Anti-FHA, POST (N= 123, 122, 117)	123	122	117	
Anti-PRN, POST (N= 122, 122, 117)	122	122	117	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Hepatitis B (anti-HBs) antibody concentrations

End point title	Anti-Hepatitis B (anti-HBs) antibody concentrations

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seroprotection cut-off assay was 10 mIU/mL.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2))

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	79	79	84	
Units: mIU/mL				
geometric mean (confidence interval 95%)	2233.3 (1479.7 to 3370.8)	2026.3 (1389.4 to 2955.2)	2685.7 (1868.8 to 3859.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentration

End point title	Anti-HBs antibody concentration

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seroprotection cut-off assay was 10 mIU/mL.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	115	115	
Units: mIU/mL				
geometric mean (confidence interval 95%)	2229.3 (1625.5 to 3057.5)	1729.8 (1240.6 to 2411.9)	3711.4 (2729.7 to 5046.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Hepatitis B (anti-HBs) antibody concentration

End point title	Anti-Hepatitis B (anti-HBs) antibody concentration

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seroprotection cut-off assay was 10 mIU/mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	74	79	84	
Units: mIU/mL				
geometric mean (confidence interval 95%)	130.3 (91.2 to 186.0)	124.4 (89.5 to 173.0)	166.4 (112.8 to 245.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). Seroprotection cut-off assay was 10 mIU/mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120	119	115	
Units: mIU/mL				
geometric mean (confidence interval 95%)	94.9 (72.2 to 124.8)	61.8 (45.7 to 83.5)	125.9 (94.6 to 167.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-Hepatitis B antigens

End point title	Number of seroprotected subjects against anti-Hepatitis B antigens

End point description:

A seroprotected subject was a subject whose antibody concentration was greater than or equal to the level defining clinical protection of 10 milli-international units per millilitre (mIU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	74	79	84	
Units: Participants	68	74	78	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-HBs antigen

End point title	Number of seroprotected subjects against anti-HBs antigen

End point description:

A seroprotected subject was a subject whose antibody concentration was greater than or equal to the level defining clinical protection of 10 milli-international units per millilitre (mIU/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booaster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	120	119	115	
Units: Participants	108	100	106	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-poliovirus types 1, 2, 3

End point title	Concentrations for anti-poliovirus types 1, 2, 3

End point description:

Concentrations were expressed as geometric mean titers (GMTs). The seroprotection cut-off of the assay was 8.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	74	80	
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, PRE (N= 69, 74, 71)	18.2 (13.7 to 24.1)	17.8 (13.5 to 23.5)	22.4 (16.8 to 29.9)	
Anti-Polio 2, PRE (N= 69, 72, 69)	12.7 (9.5 to 16.9)	17.1 (12.3 to 23.8)	16.6 (12.0 to 22.8)	
Anti-Polio, 3 PRE (N= 73, 73, 80)	24.7 (17.1 to 35.8)	16.8 (12.0 to 23.5)	26.6 (19.2 to 36.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration for anti-poliovirus types 1, 2, 3

End point title	Concentration for anti-poliovirus types 1, 2, 3

End point description:

Concentrations were expressed as geometric mean titers (GMTs). The seroprotection cut-off of the assay was 8.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	72	85	
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, POST (N= 77, 72, 85)	572.9 (435.5 to 753.6)	558.3 (422.0 to 738.8)	902.1 (698.4 to 1165.0)	
Anti-Polio 2, POST (N= 62, 61, 76)	629.7 (452.6 to 876.1)	668.7 (489.9 to 912.7)	1184.9 (901.1 to 1558.1)	
Anti-Polio 3, POST (N= 64, 63, 73)	1147.5 (846.2 to 1556.0)	614.0 (453.9 to 830.6)	1120.7 (793.0 to 1583.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-poliovirus types 1, 2 and 3

End point title	Concentrations for anti-poliovirus types 1, 2 and 3

End point description:

Concentrations were expressed as geometric mean titers (GMTs). The seroprotection cut-off of the assay was 8.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	113	107	103	
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, POST (N= 111, 107, 103)	1121.0 (904.2 to 1389.8)	1099.6 (905.2 to 1335.8)	1386.2 (1091.8 to 1760.0)	
Anti-Polio 2, POST (N= 96, 97, 87)	1485.3 (1182.4 to 1865.8)	1215.6 (973.8 to 1517.4)	1537.2 (1191.0 to 1984.1)	
Anti-Polio 3, POST (N= 113, 103, 98)	1851.2 (1473.2 to 2326.1)	1960.4 (1574.0 to 2441.5)	2376.4 (1874.2 to 3013.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration for anti-poliovirus type 1, 2 and 3

End point title	Concentration for anti-poliovirus type 1, 2 and 3

End point description:

Concentrations were expressed as geometric mean titers (GMTs). The seroprotection cut-off of the assay was 8.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	109	104	
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, PRE (N=106, 105, 99)	53.5 (39.6 to 72.4)	50.7 (37.2 to 69.2)	70.8 (52.4 to 95.8)	
Anti-Polio 2, PRE (N= 90, 93, 85)	76.6 (50.3 to 116.7)	55.0 (38.2 to 79.3)	82.7 (55.6 to 122.9)	
Anti-Polio, 3 PRE (N= 108, 109, 104)	67.8 (47.3 to 97.2)	73.8 (52.2 to 104.2)	93.9 (64.4 to 136.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Seroprotected Subjects for anti-poliovirus type 1, 2 and 3

End point title	Number of Seroprotected Subjects for anti-poliovirus type 1, 2 and 3

End point description:

A seroprotected subject was a subject whose antibody titre was greater than or equal to the level defining clinical protection of 8.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	73	74	80	
Units: Participants				
Anti-Polio 1, PRE (N= 69, 74, 71)	50	54	56	
Anti-Polio 2, PRE (N= 69, 72, 69)	38	44	44	
Anti-Polio, 3 PRE (N= 73, 73, 80)	51	43	61	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-Poliovirus type 1, 2 and 3

End point title	Number of seroprotected subjects against anti-Poliovirus type 1, 2 and 3

End point description:

A seroprotected subject was a subject whose antibody titre was greater than or equal to the level defining clinical protection of 8.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	108	109	104	
Units: Participants				
Anti-Polio 1, PRE (N= 106, 105, 99)	95	91	92	
Anti-Polio 2, PRE (n= 90, 93, 85)	78	81	74	
Anti-Polio, 3 PRE (n= 108, 109, 104)	96	99	91	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PRP antibodies

End point title	Concentrations for anti-PRP antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.15 µg /mL.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	90	
Units: µg /mL				
geometric mean (confidence interval 95%)	12.765 (9.300 to 17.520)	15.904 (11.723 to 21.576)	17.099 (12.966 to 22.550)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PRP antibody

End point title	Concentrations for anti-PRP antibody

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.15 µg /mL.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	122	118	
Units: µg /mL				
geometric mean (confidence interval 95%)	21.462 (16.650 to 27.664)	15.903 (12.132 to 20.848)	17.429 (13.429 to 22.620)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-polyribosyl-ribitol phosphate (anti-PRP) antibodies

End point title	Concentrations for anti-polyribosyl-ribitol phosphate (anti-PRP) antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.15 µg /mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	89	
Units: µg /mL				
geometric mean (confidence interval 95%)	0.173 (0.138 to 0.216)	0.175 (0.142 to 0.216)	0.236 (0.182 to 0.307)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-polyribosyl-ribitol phosphate antibodies

End point title	Concentrations for anti-polyribosyl-ribitol phosphate antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was 0.15 µg /mL.

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2))

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	117	
Units: µg /mL				
geometric mean (confidence interval 90%)	0.328 (0.262 to 0.409)	0.288 (0.227 to 0.365)	0.334 (0.254 to 0.439)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-Pertussis toxoid (anti-PT), anti-FHA, anti-PRN

End point title	Number of seropositive subjects for anti-Pertussis toxoid (anti-PT), anti-FHA, anti-PRN

End point description:

A seropositive subject was a subject whose antibody concentration was greater than or equal to (≥) the assay cut-off of 5 ELISA units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	89	
Units: Participants				
Anti-PT, PRE (N= 80, 80, 87)	68	65	78	
Anti-FHA, PRE (N= 81, 82, 88)	81	81	88	
Anti-PRN, PRE (N= 81, 81, 89)	68	69	83	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-PT, anti-FHA and anti-PRN

End point title	Number of seropositive subjects for anti-PT, anti-FHA and anti-PRN

End point description:

A seropositive subject was a subject whose antibody concentration was greater than or equal to (≥) the assay cut-off of 5 ELISA units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	117	
Units: Participants				
Anti-PT, PRE (N= 123, 121, 117)	95	94	97	
Anti-FHA, PRE (N= 123, 118, 116)	122	117	116	
Anti-PRN, PRE (N= 123, 121, 117)	98	92	105	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-PRP (anti-polyribosyl-ribitol phosphate)

End point title	Number of seroprotected subjects for anti-PRP (anti-polyribosyl-ribitol phosphate)

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	89	
Units: Participants	41	45	52	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-polyribosyl-ribitol phosphate (PRP)

End point title	Number of seroprotected subjects for anti-polyribosyl-ribitol phosphate (PRP)

End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Before (PRE) booster vaccination (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	117	
Units: Participants	92	78	81	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-pneumococcal (anti-PNE) antibodies

End point title	Concentrations for anti-pneumococcal (anti-PNE) antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seropositivity cut-off of the assay was 0.15 µg /mL. The anti-PNE serotypes assessed were 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	53	
Units: µg /mL				
geometric mean (confidence interval 95%)				
Anti- PNE 1 (N= 50, 50, 53)	2.07 (1.69 to 2.53)	2.16 (1.75 to 2.68)	2.27 (1.84 to 2.80)	
Anti- PNE 3 (N= 40, 44, 44)	0.76 (0.62 to 0.93)	0.87 (0.66 to 1.15)	0.88 (0.69 to 1.14)	
Anti- PNE 4 (N= 50, 50, 53)	1.87 (1.51 to 2.32)	1.83 (1.46 to 2.28)	2.14 (1.72 to 2.66)	
Anti- PNE 5 (N= 50, 50, 53)	1.18 (0.97 to 1.42)	1.10 (0.92 to 1.33)	1.21 (0.99 to 1.49)	
Anti- PNE 6A (N= 50, 50, 53)	7.71 (6.49 to 9.16)	6.92 (5.53 to 8.64)	8.63 (6.79 to 10.96)	
Anti- PNE 6B (N= 50, 50, 53)	4.24 (3.39 to 5.30)	4.21 (3.17 to 5.59)	4.58 (3.45 to 6.08)	
Anti- PNE 7F (N= 50, 50, 53)	3.27 (2.75 to 3.89)	3.42 (2.94 to 3.97)	4.27 (3.58 to 5.08)	
Anti- PNE 9V (N= 50, 50, 53)	1.68 (1.33 to 2.11)	1.52 (1.25 to 1.85)	1.63 (1.29 to 2.06)	
Anti- PNE 14 (N= 50, 50, 53)	8.22 (6.27 to 10.77)	8.80 (7.01 to 11.06)	8.97 (7.29 to 11.02)	
Anti- PNE 18C (N= 50, 50, 53)	1.50 (1.13 to 1.99)	1.63 (1.32 to 2.01)	1.64 (1.33 to 2.02)	
Anti- PNE 19A (N= 49, 50, 53)	7.00 (5.76 to 8.51)	8.05 (6.39 to 10.13)	6.70 (5.14 to 8.73)	
Anti- PNE 19F (N= 50, 50, 53)	7.15 (5.86 to 8.74)	7.34 (5.89 to 9.15)	6.72 (5.32 to 8.48)	
Anti- PNE 23F (N= 50, 47, 52)	3.74 (2.87 to 4.88)	4.54 (3.67 to 5.63)	3.94 (2.97 to 5.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PNE antibodies

End point title	Concentrations for anti-PNE antibodies

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seropositivity cut-off of the assay was 0.15 µg /mL. The anti-PNE serotypes assessed were 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	21	20	
Units: µg /mL				
geometric mean (confidence interval 95%)				
Anti- PNE 1 (N= 23, 21, 20)	2.54 (1.93 to 3.34)	2.47 (1.83 to 3.35)	3.47 (2.23 to 5.41)	
Anti- PNE 3 (N= 21, 18, 16)	0.76 (0.59 to 0.96)	0.82 (0.60 to 1.13)	0.92 (0.66 to 1.30)	
Anti-PNE 4 (N= 23, 21, 20)	2.03 (1.53 to 2.68)	2.10 (1.59 to 2.79)	2.57 (1.65 to 4.01)	
Anti-PNE 5 (N= 23, 21, 20)	1.26 (0.97 to 1.63)	1.24 (0.98 to 1.57)	1.29 (0.89 to 1.87)	
Anti-PNE 6A (N= 23, 21, 20)	10.64 (7.94 to 14.25)	7.67 (6.18 to 9.53)	7.47 (4.76 to 11.70)	
Anti-PNE 6B (N= 23, 21, 20)	5.04 (3.74 to 6.79)	4.56 (3.16 to 6.59)	6.62 (3.90 to 11.24)	
Anti-PNE 7F (N= 23, 21, 20)	4.20 (3.45 to 5.11)	3.97 (2.98 to 5.29)	4.67 (3.16 to 6.89)	
Anti-PNE 9V (N= 23, 21, 20)	2.20 (1.66 to 2.93)	1.42 (1.10 to 1.85)	1.85 (1.21 to 2.83)	
Anti-PNE 14 (N= 23, 21, 20)	7.47 (5.68 to 9.83)	8.12 (6.04 to 10.93)	9.28 (6.15 to 14.01)	
Anti-PNE 18C (N= 23, 21, 20)	1.80 (1.34 to 2.40)	1.52 (1.09 to 2.11)	2.09 (1.41 to 3.11)	
Anti-PNE 19A (N= 23, 21, 20)	8.79 (6.53 to 11.82)	6.22 (4.99 to 7.76)	9.10 (5.23 to 15.84)	
Anti-PNE 19F (N= 23, 21, 20)	8.09 (5.48 to 11.95)	7.11 (5.21 to 9.70)	5.56 (3.38 to 9.14)	
Anti-PNE 23F (N= 23, 21, 20)	5.31 (4.29 to 6.57)	4.00 (3.05 to 5.24)	5.82 (3.59 to 9.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-pneumococcal (anti-PNE) serotypes

End point title	Number of seropositive subjects for anti-pneumococcal (anti-PNE) serotypes

End point description:

A seropositive subject was defined as a vaccinated subject who had anti- pneumococcal antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL). The anti-PNE serotypes assessed were 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	53	
Units: Participants				
Anti- PNE 1 (N= 50, 50, 53)	50	50	53	
Anti- PNE 3 (N= 40, 44, 44)	40	43	43	
Anti- PNE 4 (N= 50, 50, 53)	50	50	53	
Anti- PNE 5 (N= 50, 50, 53)	50	50	53	
Anti- PNE 6A (N= 50, 50, 53)	50	50	53	
Anti- PNE 6B (N= 50, 50, 53)	50	49	53	
Anti- PNE 7F (N= 50, 50, 53)	50	50	53	
Anti- PNE 9V (N= 50, 50, 53)	50	50	53	
Anti- PNE 14 (N= 50, 50, 53)	49	50	53	
Anti- PNE 18C (N= 50, 50, 53)	49	50	53	
Anti- PNE 19A (N= 49, 50, 53)	49	50	53	
Anti- PNE 19F (N= 50, 50, 53)	50	50	53	
Anti- PNE 23F (N= 50, 47, 52)	50	47	52	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for anti-PNE serotypes

End point title	Number of seropositive subjects for anti-PNE serotypes

End point description:

A seropositive subject was defined as a vaccinated subject who had anti- pneumococcal antibody concentrations ≥ 0.15 micrograms per milliliter (µg/mL). The anti-PNE serotypes assessed were 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	21	20	
Units: Participants				
Anti- PNE 1 (N= 23, 21, 20)	23	21	20	
Anti- PNE 3 (N= 21, 18, 16)	21	18	16	
Anti-PNE 4 (N= 23, 21, 20)	23	21	20	
Anti-PNE 5 (N= 23, 21, 20)	23	21	20	

Anti-PNE 6A (N= 23, 21, 20)	23	21	20	
Anti-PNE 6B (N= 23, 21, 20)	23	21	20	
Anti-PNE 7F (N= 23, 21, 20)	23	21	20	
Anti-PNE 9V (N= 23, 21, 20)	23	21	20	
Anti-PNE 14 (N= 23, 21, 20)	23	21	20	
Anti-PNE 18C (N= 23, 21, 20)	23	21	20	
Anti-PNE 19A (N= 23, 21, 19)	23	21	19	
Anti-PNE 19F (N= 23, 21, 20)	23	21	20	
Anti-PNE 23F (N= 23, 21, 20)	23	21	20	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster response to anti-pertussis antigens (anti-PT, anti-FHA and anti-PRN)

End point title	Number of subjects with booster response to anti-pertussis antigens (anti-PT, anti-FHA and anti-PRN)

End point description:

Booster response defined as : – For initially seronegative subjects, antibody concentration ≥ 5 EL.U/mL one month after booster vaccination – For initially seropositive subjects, antibody concentration at Post-booster ≥ 2 fold the pre-vaccination antibody concentration

End point type	Secondary

End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	81	82	88	
Units: Participants				
Anti-PT (N= 78, 79, 86)	72	77	86	
Anti-FHA (N= 81, 82, 88)	79	81	87	
Anti-PRN (N= 81, 80, 88)	81	80	87	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with booster response to anti-pertussis antigens

End point title	Number of subjects with booster response to anti-pertussis antigens

End point description:

Booster response defined as : – For initially seronegative subjects, antibody concentration ≥ 5 EL.U/mL one month after booster vaccination – For initially seropositive subjects, antibody concentration at Post-booster ≥ 2 fold the pre-vaccination antibody concentration

End point type	Secondary

End point timeframe:

1 month poste booster vaccination (POST) (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	123	121	116	
Units: Subjects				
Anti-PT (N= 118, 121, 115)	118	119	110	
Anti-FHA (N= 123, 118, 115)	120	115	113	
Anti-PRN (N= 122, 121, 116)	121	120	115	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited local symptoms

End point title	Number of subjects reporting any solicited local symptoms

End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any = occurrence of any local symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period. (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85	88	99	
Units: Participants				
Any pain (N= 85, 88, 99)	56	67	63	
Any redness (N= 85, 88, 99)	55	56	59	
Any swelling (N= 85, 88, 99)	45	43	48	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited local symptom

End point title	Number of subjects reporting any solicited local symptom

End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any = occurrence of any local symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period. (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	130	124	
Units: Participants				
Any pain (N= 131, 130, 124)	76	66	64	
Any redness (N= 131, 130, 124)	47	36	40	
Any swelling (N= 131, 130, 124)	43	34	38	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited general symptoms

End point title	Number of subjects reporting any solicited general symptoms

End point description:

Solicited local symptoms assessed were drowsiness, irritability/fussiness, loss of appetite and fever [axillary temperature above (≥) 37.5 degrees Celsius (°C)]. Any = occurrence of any local symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period. (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85	88	99	
Units: Participants				
Any drowsiness (N= 85, 88, 99)	54	47	47	
Any irritability/fussiness (N= 85, 88, 99)	69	73	74	
Any loss of appetite (N= 85, 88, 99)	43	45	46	
Any fever (N= 85, 88, 99)	42	41	37	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited general symptom

End point title	Number of subjects reporting any solicited general symptom

End point description:

Solicited local symptoms assessed were drowsiness, irritability/fussiness, loss of appetite and fever [axillary temperature above (≥) 37.5 degrees Celsius (°C)]. Any = occurrence of any local symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period. (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	130	124	
Units: Participants				
Any drowsiness (N= 131, 130, 124)	52	40	40	
Any irritability/fussiness (N= 131, 130, 124)	66	58	62	
Any loss of appetite (N= 131, 130, 124)	42	37	34	
Any fever (N= 131, 130, 124)	58	50	52	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited adverse events (AEs)

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

End point description:

An unsolicited AE is any AE (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any = occurrence of an AE regardless of intensity grade or relationship to study vaccination.

End point type	Secondary

End point timeframe:

Within the 31-day (Days 0-30) follow up period after vaccination. (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85	88	99	
Units: Participants	42	39	67	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited AEs

End point title	Number of subjects reporting any unsolicited AEs

End point description:

An unsolicited AE is any AE (i.e. any untoward medical occurrence in a patient or clinical investigation subject, temporally associated with use of a medicinal product, whether or not considered related to the medicinal product) reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any = occurrence of an AE regardless of intensity grade or relationship to study vaccination.

End point type	Secondary

End point timeframe:

Within the 31-day (Days 0-30) follow up period after vaccination. (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	130	124	
Units: Participants	38	27	31	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any serious adverse events (SAEs)

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

End point description:

SAEs assessed include medical occurrences that results in death, are life threatening, require hospitalization or prolongation of hospitalization, results in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subjects. Any SAE = any SAE regardless of assessment of relationship to study vaccination.

End point type	Secondary

End point timeframe:

During the entire study period (Days 0-30). (subjects enrolled before protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	85	88	99	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any SAEs

End point title	Number of subjects reporting any SAEs

End point description:

SAEs assessed include medical occurrences that results in death, are life threatening, require hospitalization or prolongation of hospitalization, results in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subjects. Any SAE = any SAE regardless of assessment of relationship to study vaccination.

End point type	Secondary

End point timeframe:

During the entire study period (Days 0-30). (subjects enrolled after protocol amendment 2)

End point values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	130	124	
Units: Participants	0	2	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: 4-day follow-up period after vaccination; unsolicited AEs: 31-day follow-up period after vaccination; SAEs: during the entire study period (Days 0-30).

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	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	GSK217744 Group 1(Before protocol amendment 2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of GSK217744 formulation A vaccine (for subjects vaccinated before Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 2(Before Protocol Amendment2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of GSK217744 formulation B vaccine (for subjects vaccinated before Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	Infanrix hexa Group(Before Protocol Amendment2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 1(After Protocol Amendment2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation A vaccine in the primary study and a booster dose of Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	GSK217744 Group 2(After Protocol Amendment2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the GSK217744 formulation B vaccine in the primary study and a booster dose of Infanrix hexa vaccine (for subjects vaccinated after Protocol Amendment 2) in this study, coadministered with a booster dose of Prevenar 13. The Infanrix hexa/GSK217744 and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively.

Reporting group title	Infanrix hexa Group(After Protocol Amendment2)

Reporting group description:

Subjects aged between and including 12 and 15 months at the time of booster vaccination who received the Infanrix hexa vaccine in the primary study and a booster dose of Infanrix hexa in this study, co-administered with a booster dose of Prevenar 13. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively

Serious adverse events	GSK217744 Group 1(Before protocol amendment 2)	GSK217744 Group 2(Before Protocol Amendment2)	Infanrix hexa Group(Before Protocol
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 85 (0.00%)	0 / 88 (0.00%)	0 / 99 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia	Additional description: SAE reported in subjects enrolled after protocol amendment 2.		
subjects affected / exposed	0 / 85 (0.00%)	0 / 88 (0.00%)	0 / 99 (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
Metabolism and nutrition disorders			
Dehydration	Additional description: SAE reported in subjects enrolled after protocol amendment 2.		
subjects affected / exposed	0 / 85 (0.00%)	0 / 88 (0.00%)	0 / 99 (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

Serious adverse events	GSK217744 Group 1(After Protocol Amendment2)	GSK217744 Group 2(After Protocol Amendment2)	Infanrix hexa Group(After Protocol Amendment2)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 131 (0.00%)	2 / 130 (1.54%)	0 / 124 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia	Additional description: SAE reported in subjects enrolled after protocol amendment 2.		
subjects affected / exposed	0 / 131 (0.00%)	2 / 130 (1.54%)	0 / 124 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration	Additional description: SAE reported in subjects enrolled after protocol amendment 2.		
subjects affected / exposed	0 / 131 (0.00%)	1 / 130 (0.77%)	0 / 124 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	GSK217744 Group 1(Before protocol amendment 2)	GSK217744 Group 2(Before Protocol Amendment2)	Infanrix hexa Group(Before Protocol
Total subjects affected by non-serious adverse events			
subjects affected / exposed	85 / 85 (100.00%)	85 / 88 (96.59%)	96 / 99 (96.97%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	54 / 85 (63.53%)	47 / 88 (53.41%)	47 / 99 (47.47%)
occurrences (all)	54	47	47
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	7 / 85 (8.24%)	3 / 88 (3.41%)	5 / 99 (5.05%)
occurrences (all)	7	3	5
Pain			
subjects affected / exposed	56 / 85 (65.88%)	67 / 88 (76.14%)	63 / 99 (63.64%)
occurrences (all)	56	67	63
Swelling			
subjects affected / exposed	45 / 85 (52.94%)	43 / 88 (48.86%)	48 / 99 (48.48%)
occurrences (all)	45	43	48
Pyrexia			
subjects affected / exposed	44 / 85 (51.76%)	45 / 88 (51.14%)	39 / 99 (39.39%)
occurrences (all)	44	45	39
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 85 (5.88%)	6 / 88 (6.82%)	4 / 99 (4.04%)
occurrences (all)	5	6	4
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	55 / 85 (64.71%)	56 / 88 (63.64%)	59 / 99 (59.60%)
occurrences (all)	55	56	59
Psychiatric disorders			
Irritability/fussiness			
subjects affected / exposed	69 / 85 (81.18%)	73 / 88 (82.95%)	74 / 99 (74.75%)
occurrences (all)	69	73	74
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	3 / 85 (3.53%)	1 / 88 (1.14%)	7 / 99 (7.07%)
occurrences (all)	3	1	7
Nasopharyngitis			

subjects affected / exposed	4 / 85 (4.71%)	2 / 88 (2.27%)	5 / 99 (5.05%)
occurrences (all)	4	2	5
Otitis media			
subjects affected / exposed	6 / 85 (7.06%)	11 / 88 (12.50%)	11 / 99 (11.11%)
occurrences (all)	6	11	11
Upper respiratory tract infection			
subjects affected / exposed	6 / 85 (7.06%)	7 / 88 (7.95%)	9 / 99 (9.09%)
occurrences (all)	6	7	9
Gastroenteritis			
subjects affected / exposed	2 / 85 (2.35%)	2 / 88 (2.27%)	5 / 99 (5.05%)
occurrences (all)	2	2	5
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	43 / 85 (50.59%)	45 / 88 (51.14%)	46 / 99 (46.46%)
occurrences (all)	43	45	46

Non-serious adverse events	GSK217744 Group 1(After Protocol Amendment2)	GSK217744 Group 2(After Protocol Amendment2)	Infanrix hexa Group(After Protocol Amendment2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	118 / 131 (90.08%)	103 / 130 (79.23%)	104 / 124 (83.87%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	52 / 131 (39.69%)	40 / 130 (30.77%)	40 / 124 (32.26%)
occurrences (all)	52	40	40
General disorders and administration site conditions			
Injection site induration			
subjects affected / exposed	4 / 131 (3.05%)	0 / 130 (0.00%)	0 / 124 (0.00%)
occurrences (all)	4	0	0
Pain			
subjects affected / exposed	76 / 131 (58.02%)	66 / 130 (50.77%)	64 / 124 (51.61%)
occurrences (all)	76	66	64
Swelling			
subjects affected / exposed	43 / 131 (32.82%)	34 / 130 (26.15%)	38 / 124 (30.65%)
occurrences (all)	43	34	38
Pyrexia			
subjects affected / exposed	59 / 131 (45.04%)	51 / 130 (39.23%)	52 / 124 (41.94%)
occurrences (all)	59	51	52

Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	2 / 131 (1.53%) 2	2 / 130 (1.54%) 2	4 / 124 (3.23%) 4
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	47 / 131 (35.88%) 47	36 / 130 (27.69%) 36	40 / 124 (32.26%) 40
Psychiatric disorders Irritability/fussiness subjects affected / exposed occurrences (all)	66 / 131 (50.38%) 66	58 / 130 (44.62%) 58	62 / 124 (50.00%) 62
Infections and infestations Conjunctivitis subjects affected / exposed occurrences (all)	0 / 131 (0.00%) 0	0 / 130 (0.00%) 0	0 / 124 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	13 / 131 (9.92%) 13	9 / 130 (6.92%) 9	8 / 124 (6.45%) 8
Otitis media subjects affected / exposed occurrences (all)	3 / 131 (2.29%) 3	3 / 130 (2.31%) 3	2 / 124 (1.61%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 131 (0.76%) 1	1 / 130 (0.77%) 1	4 / 124 (3.23%) 4
Gastroenteritis subjects affected / exposed occurrences (all)	1 / 131 (0.76%) 1	1 / 130 (0.77%) 1	1 / 124 (0.81%) 1
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	42 / 131 (32.06%) 42	37 / 130 (28.46%) 37	34 / 124 (27.42%) 34

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 April 2012	After protocol amendment 2, all subjects yet to receive a booster dose in the present study will be administered the licensed formulation of Infanrix hexa.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported