

**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	v2
This version publication date	11 August 2016
First version publication date	01 February 2015
Version creation reason	• Correction of full data set Data (typos) were corrected.

Trial information**Trial identification**

Sponsor protocol code	114843
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01453998
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 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089904466, 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 occurred 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:

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.

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	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:

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.

Investigational medicinal product name	Biological: GSK217744
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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 title	GSK217744 Group 2
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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:

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.

Investigational medicinal product name	GSK217744
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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 title	Infanrix hexa Group
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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:

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.

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

Dosage and administration details:

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.

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

Period 2

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

Arms

Are arms mutually exclusive?	No
Arm title	GSK217744 Group 1
Arm description: -	
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	
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 co-administered dose, intramuscular into the left side of the thigh	
Investigational medicinal product name	GSK217744
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use
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Dosage and administration details:

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

Arm title	GSK217744 Group 2
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	Infanrix hexa™
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Injection
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Routes of administration	Intramuscular use
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Dosage and administration details:

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

Arm title	Infanrix hexa Group
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Arm description: -

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

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

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline 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.

Number of subjects in period 2	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	-	-

Baseline characteristics

Reporting groups^[1]

Reporting group title	GSK217744 Group 1
Reporting group description: -	
Reporting group title	GSK217744 Group 2
Reporting group description: -	
Reporting group title	Infanrix hexa Group
Reporting group description: -	

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects 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.

Reporting group values	GSK217744 Group 1	GSK217744 Group 2	Infanrix hexa Group
Number of subjects	131	130	124
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: months			
arithmetic mean	14.1	13.9	14
standard deviation	± 0.6	± 0.6	± 0.6
Gender categorical Units: Subjects			
Female	61	76	53
Male	70	54	71

Reporting group values	Total		
Number of subjects	385		
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years			

85 years and over			
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Age continuous Units: months arithmetic mean standard deviation			
Gender categorical Units: Subjects			
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: -	
Reporting group title	GSK217744 Group 2
Reporting group description: -	
Reporting group title	Infanrix hexa Group
Reporting group description: -	

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-D, POST	81	82	90	
Anti-T, POST	81	82	90	

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) ^[2]
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End point description:

A seroprotected subject was defined as a vaccinated subject who had anti-PRP antibody concentrations ≥ 0.15 micrograms per milliliter ($\mu\text{g}/\text{mL}$).

End point type	Primary
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End point timeframe:

1 month post booster vaccination (POST) (subjects enrolled before 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-PRP, POST	81	82	90	

Statistical analyses

No statistical analyses for this end point

Primary: Concentrations for anti-PRP antibodies

End point title	Concentrations for anti-PRP antibodies ^[3]
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End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection cut-off of the assay was $0.15 \mu\text{g}/\text{mL}$.

End point type	Primary
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Units:µg /mL				
geometric mean (confidence interval 95%)				
Anti-PRP, POST	12.765 (9.3 to 17.52)	15.904 (11.723 to 21.576)	17.099 (12.966 to 22.55)	

Statistical analyses

No statistical analyses for this end point

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 ^[4]
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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
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-D, POST	123	122	118	
Anti-T, POST	123	122	118	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin (anti-PRN) antibody concentrations

End point title	Anti-Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA), anti-Pertactin (anti-PRN) antibody concentrations ^[5]
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End point description:

End point type	Primary
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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 (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 (368.1 to 485.9)	
Anti-PRN, POST [N=81; 81; 89]	213 (178.1 to 254.7)	180 (154.2 to 210.1)	372.9 (309.3 to 449.5)	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PT, Anti-FHA, anti-PRN antibody concentrations

End point title	Anti-PT, Anti-FHA, anti-PRN antibody concentrations ^[6]
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End point description:

End point type	Primary
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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)	93.6 (83.1 to 105.5)	132.6 (114.9 to 153)	

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 (154.8 to 211.7)	401.1 (342.2 to 470)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations equal to or above (\geq) the cut-off value of 5 ELISA units per millilitre (EL.U/mL)

End point title	Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations equal to or above (\geq) the cut-off value of 5 ELISA units per millilitre (EL.U/mL) ^[7]
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End point description:

End point type	Primary
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
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

Primary: Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL

End point title	Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL ^[8]
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End point description:

End point type	Primary
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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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
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

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

End point title Anti-Hepatitis B (anti-HBs) antibody concentrations^[9]

End point description:

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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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%)				
Anti-HBs, POST	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

Primary: Number of seroprotected subjects against anti-HBs antigens

End point title Number of seroprotected subjects against anti-HBs antigens^[10]

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:

[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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-HBs, POST	78	78	84	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-HBs antibody concentrations

End point title Anti-HBs antibody concentrations^[11]

End point description:

End point type Primary

End point timeframe:

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

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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%)				
Anti-HBs, POST	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

Primary: Number of seroprotected subjects against anti-HBs antigens

End point title | Number of seroprotected subjects against anti-HBs antigens^[12]

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:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-HBs, POST	123	114	114	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-Polio virus type 1, 2 and 3 (anti-Polio 1, anti-Polio 2 and anti-Polio 3) antibody titers

End point title | Anti-Polio virus type 1, 2 and 3 (anti-Polio 1, anti-Polio 2 and anti-Polio 3) antibody titers^[13]

End point description:

End point type | Primary

End point timeframe:

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

Notes:

[13] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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 to 738.8)	902.1 (698.4 to 1165)	

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)	614 (453.9 to 830.6)	1120.7 (793 to 1583.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against Polio type 1, 2 and 3 antigens

End point title	Number of seroprotected subjects against Polio type 1, 2 and 3 antigens ^[14]
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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
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End point timeframe:

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

Notes:

[14] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
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: Anti-Polio 1, anti-Polio 2 and anti-Polio 3 antibody titers

End point title	Anti-Polio 1, anti-Polio 2 and anti-Polio 3 antibody titers ^[15]
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End point description:

End point type	Primary
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End point timeframe:

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

Notes:

[15] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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 (904.2 to 1389.8)	1099.6 (905.2 to 1335.8)	1386.2 (1091.8 to 1760)	
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 to 1984.1)	
Anti-Polio 3, POST [N=113;103;98]	1851.2 (1473.2 to 2326.1)	1960.4 (1574 to 2441.5)	2376.4 (1874.2 to 3013.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-Polio 1, 2 and 3

End point title	Number of seroprotected subjects against anti-Polio 1, 2 and
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End point description:

End point type	Primary
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End point timeframe:

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

Notes:

[16] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
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: Anti- polyribosyl-ribitol phosphate (anti-PRP) antibody concentrations

End point title	Anti- polyribosyl-ribitol phosphate (anti-PRP) antibody concentrations ^[17]
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End point description:

End point type	Primary
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End point timeframe:

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

Notes:

[17] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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%)				
Anti-PRP, POST	21.462 (16.65 to 27.664)	15.903 (12.132 to 20.848)	17.429 (13.429 to 22.62)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects against anti-PRP antigens

End point title	Number of seroprotected subjects against anti-PRP antigens ^[18]
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End point description:

A seroprotected subject was a subject whose antibody concentration was greater than or equal to $\geq 0.15 \mu\text{g/mL}$

End point type	Primary
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End point timeframe:

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

Notes:

[18] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

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: Subjects				
Anti-PRP, POST	122	122	117	

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.
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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
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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 PRE [N=81;82;89]	0.357 (0.305 to 0.419)	0.445 (0.381 to 0.52)	0.401 (0.343 to 0.468)	
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 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)	
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)	

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
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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
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End point timeframe:

Before (PRE) and 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: Units:IU/mL				
geometric mean (confidence interval 95%)				
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 0.36)	
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, PRE [N=123;121;117]	0.364 (0.313 to 0.422)	0.332 (0.289 to 0.38)	0.331 (0.285 to 0.383)	
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)	

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 ($\mu\text{g/mL}$). 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: Subjects				
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: 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 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: 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 2.8)	
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)	1.1 (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 5.3)	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)	8.8 (7.01 to 11.06)	8.97 (7.29 to 11.02)	
Anti- PNE 18C [N=50;50;53]	1.5 (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 (5.76 to 8.51)	8.05 (6.39 to 10.13)	6.7 (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: Number of seropositive subjects for anti-pneumococcal (anti-PNE) serotypes

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

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

End point type	Secondary
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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: Subjects				
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: Concentrations for anti-PNE antibodies.

End point title	Concentrations for anti-PNE antibodies.
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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: 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 (0.6 to 1.13)	0.92 (0.66 to 1.3)	
Anti-PNE 4 [N=23;21;20]	2.03 (1.53 to 2.68)	2.1 (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 11.7)	
Anti-PNE 6B [N=23;21;20]	5.04 (3.74 to 6.79)	4.56 (3.16 to 6.59)	6.62 (3.9 to 11.24)	
Anti-PNE 7F [N=23;21;20]	4.2 (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]	2.2 (1.66 to 2.93)	1.42 (1.1 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]	1.8 (1.34 to 2.4)	1.52 (1.09 to 2.11)	2.09 (1.41 to 3.11)	
Anti-PNE 19A [N=23;21;19]	8.79 (6.53 to 11.82)	6.22 (4.99 to 7.76)	9.1 (5.23 to 15.84)	
Anti-PNE 19F [N=23;21;20]	8.09 (5.48 to 11.95)	7.11 (5.21 to 9.7)	5.56 (3.38 to 9.14)	
Anti-PNE 23F [N=23;21;20]	5.31 (4.29 to 6.57)	4 (3.05 to 5.24)	5.82 (3.59 to 9.44)	

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: Subjects				
Any pain	56	67	63	
Any redness	55	56	59	
Any swelling	45	43	48	

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 (\geq) 37.5 degrees Celsius ($^{\circ}$ 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: Subjects				
Any drowsiness	54	47	47	
Any irritability/fussiness	69	73	74	
Any loss of appetite	43	45	46	
Any fever	42	41	37	

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: Subjects				
Any AE(s)	42	39	67	

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: Subjects				
Any SAE(s)	0	0	0	

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 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: Subjects				
Any pain	76	66	64	
Any redness	47	36	40	
Any swelling	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 (\geq) 37.5 degrees Celsius ($^{\circ}$ 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: Subjects				
Any drowsiness	52	40	40	
Any irritability/fussiness	66	58	62	
Any loss of appetite	42	37	34	
Any fever	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)
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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
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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: Subjects				
Any AE(s)	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)
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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
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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: Subjects				
Any SAE(s)	1	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Anti-D/Anti-T antigens

End point title	Number of seroprotected subjects against Anti-D/Anti-T antigens
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End point description:

End point type	Secondary
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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: Subjects				
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: Number of seroprotected subjects against Anti-D/Anti-T antigens

End point title	Number of seroprotected subjects against Anti-D/Anti-T antigens
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End point description:

End point type	Secondary
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End point timeframe:

Before (PRE) booster 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	81	82	89	
Units: Subjects				
Anti-D PRE [N=81;82;89]	78	80	84	
Anti-T PRE [N=81;82;89]	76	78	85	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PT, Anti-FHA, anti-PRN antibody concentrations

End point title	Anti-PT, Anti-FHA, anti-PRN antibody concentrations
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End point description:

End point type	Secondary
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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)	
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 to 22.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PT, Anti-FHA, anti-PRN antibody concentrations

End point title	Anti-PT, Anti-FHA, anti-PRN antibody concentrations
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End point description:

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 (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 to 18.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL

End point title	Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL
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End point description:

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: Subjects				
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 subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL

End point title | Number of subjects anti-PT, anti-FHA, anti-PRN antibody concentrations \geq the cut-off value of 5 EL.U/mL

End point description:

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

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

End point description:

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%)				
Anti-HBs, PRE	130.3 (91.2 to 186)	124.4 (89.5 to 173)	166.4 (112.8 to 245.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-HBs antigens

End point title | Number of seroprotected subjects against anti-HBs 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: Subjects				
Anti-HBs, PRE	68	74	78	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations

End point title | Anti-HBs antibody concentrations

End point description:

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%)				
Anti-HBs, PRE	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-HBs antigens

End point title	Number of seroprotected subjects against anti-HBs antigens
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End point description:

End point type	Secondary
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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: Subjects				
Anti-HBs, PRE	113	103	108	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Polio virus type 1, 2 and 3 (anti-Polio 1, anti-Polio 2 and anti-Polio 3) antibody titers

End point title	Anti-Polio virus type 1, 2 and 3 (anti-Polio 1, anti-Polio 2 and anti-Polio 3) antibody titers
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End point description:

End point type	Secondary
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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 to 22.8)	
Anti-Polio, 3 PRE [N=73;73;80]	24.7 (17.1 to 35.8)	16.8 (12 to 23.5)	26.6 (19.2 to 36.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Polio type 1, 2 and 3 antigens

End point title	Number of seroprotected subjects against Polio type 1, 2 and 3 antigens
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End point description:

End point type	Secondary
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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: Subjects				
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: Anti-Polio 1, anti-Polio 2 and anti-Polio 3 antibody titers

End point title	Anti-Polio 1, anti-Polio 2 and anti-Polio 3 antibody titers
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End point description:

End point type	Secondary
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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 (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 against anti-Polio 1, 2 and 3

End point title | Number of seroprotected subjects against anti-Polio 1, 2 and 3

End point description:

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: Subjects				
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:	
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%)				
Anti-PRP, PRE	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: Number of seroprotected subjects for anti-PRP

End point title	Number of seroprotected subjects for anti-PRP
End point description:	
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: Subjects				
Anti-PRP, PRE	41	45	52	

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
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End point description:

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 95%)				
Anti-PRP, PRE	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 seroprotected subjects against anti-PRP antigens

End point title Number of seroprotected subjects against anti-PRP antigens

End point description:

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: Subjects				
Anti-PRP, PRE	92	78	81	

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 \geq 5 EL.U/mL one month after booster vaccination	
– For initially seropositive subjects, antibody concentration at Post-booster \geq 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: Subjects				
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 (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 \geq 5 EL.U/mL one month after booster vaccination	
– For initially seropositive subjects, antibody concentration at Post-booster \geq 2 fold the pre-vaccination antibody concentration	
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	121	116	
Units: Subjects				
Anti-PT [N=118;120;115]	118	119	110	
Anti-FHA [N=123;118;115]	120	115	113	

Anti-PRN [N=122;121;116]	122	121	116	
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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:

As there were no SAEs reported before protocol amendment 2, the number of subjects at risk for each reported SAE was the total number of subjects enrolled after the protocol amendment. The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	16

Reporting groups

Reporting group title	GSK217744 Group 2
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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	GSK217744 Group 1
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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	Infanrix hexa Group
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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, coadministered 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 2	GSK217744 Group 1	Infanrix hexa Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 218 (0.46%)	0 / 266 (0.00%)	0 / 223 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia			

subjects affected / exposed ^[1]	1 / 130 (0.77%)	0 / 131 (0.00%)	0 / 124 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed ^[2]	1 / 130 (0.77%)	0 / 131 (0.00%)	0 / 124 (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

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled after protocol amendment 2, corresponding to a total number of 385.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled after protocol amendment 2, corresponding to a total number of 385.

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

Non-serious adverse events	GSK217744 Group 2	GSK217744 Group 1	Infanrix hexa Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	73 / 218 (33.49%)	76 / 266 (28.57%)	74 / 223 (33.18%)
General disorders and administration site conditions			
Pain (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[3]	66 / 130 (50.77%)	76 / 131 (58.02%)	64 / 124 (51.61%)
occurrences (all)	66	76	64
Redness (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[4]	36 / 130 (27.69%)	47 / 131 (35.88%)	40 / 124 (32.26%)
occurrences (all)	36	47	40
Swelling (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[5]	34 / 130 (26.15%)	43 / 131 (32.82%)	38 / 124 (30.65%)
occurrences (all)	34	43	38
Drowsiness (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[6]	40 / 130 (30.77%)	52 / 131 (39.69%)	40 / 124 (32.26%)
occurrences (all)	40	52	40
Irritability/fussiness (Symptom			

reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[7]	58 / 130 (44.62%)	66 / 131 (50.38%)	62 / 124 (50.00%)
occurrences (all)	58	66	62
Loss of appetite (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[8]	37 / 130 (28.46%)	42 / 131 (32.06%)	34 / 124 (27.42%)
occurrences (all)	37	42	34
Fever (Symptom reported in subjects enrolled after protocol amendment 2.)			
subjects affected / exposed ^[9]	50 / 130 (38.46%)	58 / 131 (44.27%)	52 / 124 (41.94%)
occurrences (all)	50	58	52
Diarrhoea			
subjects affected / exposed ^[10]	6 / 88 (6.82%)	5 / 85 (5.88%)	4 / 99 (4.04%)
occurrences (all)	6	5	4
Injection site induration			
subjects affected / exposed ^[11]	3 / 88 (3.41%)	7 / 85 (8.24%)	5 / 99 (5.05%)
occurrences (all)	3	7	5
Pyrexia			
subjects affected / exposed ^[12]	5 / 88 (5.68%)	4 / 85 (4.71%)	5 / 99 (5.05%)
occurrences (all)	5	4	5
Pain (Symptom reported in subjects enrolled before protocol amendment 2)			
subjects affected / exposed ^[13]	67 / 88 (76.14%)	56 / 85 (65.88%)	63 / 99 (63.64%)
occurrences (all)	67	56	63
Redness (Symptom reported in subjects enrolled before protocol amendment 2)			
subjects affected / exposed ^[14]	56 / 88 (63.64%)	55 / 85 (64.71%)	59 / 99 (59.60%)
occurrences (all)	56	55	59
Swelling (Symptom reported in subjects enrolled before protocol amendment 2)			
subjects affected / exposed ^[15]	43 / 88 (48.86%)	45 / 85 (52.94%)	48 / 99 (48.48%)
occurrences (all)	43	45	48
Drowsiness (Symptom reported in subjects enrolled before protocol amendment 2)			

subjects affected / exposed ^[16] occurrences (all)	47 / 88 (53.41%) 47	54 / 85 (63.53%) 54	47 / 99 (47.47%) 47
Irritability/fussiness (Symptom reported in subjects enrolled before protocol amendment 2) subjects affected / exposed ^[17] occurrences (all)	73 / 88 (82.95%) 73	69 / 85 (81.18%) 69	74 / 99 (74.75%) 74
Loss of appetite (Symptom reported in subjects enrolled before protocol amendment 2) subjects affected / exposed ^[18] occurrences (all)	45 / 88 (51.14%) 45	43 / 85 (50.59%) 43	46 / 99 (46.46%) 46
Fever (Symptom reported in subjects enrolled before protocol amendment 2) subjects affected / exposed ^[19] occurrences (all)	41 / 88 (46.59%) 41	42 / 85 (49.41%) 42	37 / 99 (37.37%) 37
Eye disorders Conjunctivitis subjects affected / exposed ^[20] occurrences (all)	0 / 88 (0.00%) 0	3 / 85 (3.53%) 3	7 / 99 (7.07%) 7
Infections and infestations Nasopharyngitis (AE reported in subjects enrolled after protocol amendment 2) subjects affected / exposed ^[21] occurrences (all)	9 / 130 (6.92%) 9	13 / 131 (9.92%) 13	8 / 124 (6.45%) 8
Otitis media subjects affected / exposed ^[22] occurrences (all)	11 / 88 (12.50%) 11	6 / 85 (7.06%) 6	11 / 99 (11.11%) 11
Upper respiratory tract infection subjects affected / exposed ^[23] occurrences (all)	7 / 88 (7.95%) 7	6 / 85 (7.06%) 6	9 / 99 (9.09%) 9
Nasopharyngitis (AE reported in subjects enrolled before protocol amendment 2) subjects affected / exposed ^[24] occurrences (all)	2 / 88 (2.27%) 2	4 / 85 (4.71%) 4	5 / 99 (5.05%) 5
Gastroenteritis subjects affected / exposed ^[25] occurrences (all)	2 / 88 (2.27%) 2	2 / 85 (2.35%) 2	5 / 99 (5.05%) 5

corresponding to a total number of 272.

[18] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[19] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[20] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[21] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled after protocol amendment 2, corresponding to a total number of 385.

[22] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[23] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[24] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

[25] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed separately on subjects enrolled before protocol amendment 2, corresponding to a total number of 272.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 October 2011	<ol style="list-style-type: none">1. At the discretion of GSK Biologicals, pneumococcal testing may be done at a GSK Biologicals laboratory or the World Health Organisation (WHO) reference laboratory. Since the 22F-inhibition ELISA assay used at the WHO reference laboratory has a different assay cut-off, different thresholds are mentioned in the statistical analysis description. The threshold for the 22F-inhibition non-GSK ELISA assay performed at the WHO reference laboratory is 0.35 µg/ml.2. In order to simplify study management activities, the subjects will be given new treatment numbers in the present booster study.3. Exploratory statistical comparisons will be based on 97.5% CI instead of 95% to be aligned with the study objective criteria.
12 April 2012	<ol style="list-style-type: none">1. Due to the increased incidence of fever observed with the new formulations of the DTPa-HBV-IPV/Hib vaccine in the primary vaccination study 113948 (DTPa-HBV-IPV-124), all subjects yet to receive a booster dose in the present study will be administered the licensed formulation of Infanrix hexa.2. Because the safety and immunogenicity of commercial vaccines administered after Formulation A or Formulation B is unknown, this study will continue to ensure the safety of the subjects and adequate immune responses to the booster dose of Infanrix hexa.3. SBIR will be used to allocate new treatment numbers corresponding to Infanrix hexa vaccine to all newly enrolled subjects after amendment 2.4. After amendment 2, all subjects will receive Infanrix hexa. Accordingly less than half of the subjects can contribute to the initial study objectives leading to a study power lower than 50%. For this reason, separate analyses of the cohort enrolled pre and post amendment will be performed. These analyses will be descriptive without study group comparisons.
15 May 2012	At the European Medicines Agency's (EMA) request, GSK Biologicals has updated its procedure for emergency unblinding during the conduct of a clinical study. According to the revised procedure, the responsibility and the decision to break the treatment code in emergency situations resides solely with the investigator and consequently, the investigator will have full authority to break the treatment code.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported