Clinical trial results:
A phase II, open-label, randomised, multicentre study to evaluate the safety and immunogenicity of GlaxoSmithKline Biologicals' DTPa-HBV-IPV/Hib-MenC-TT vaccine, when given to healthy infants at 2, 4 and 12 months of age.

Summary

EudraCT number	2009-016635-36
Trial protocol	FR DE
Global end of trial date	11 October 2011

Results information

Result version number	v2 (current)
This version publication date	16 September 2018
First version publication date	06 June 2015
Version creation reason	• Correction of full data set Minor corrections of the full study results.

Trial information

Trial identification

Sponsor protocol code	113615

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01090453
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 September 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 October 2011
Global end of trial reached?	Yes
Global end of trial date	11 October 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate non-inferiority of the GSK2202083A vaccine when compared to the control group, in terms of immune response to Hib and MenC antigens, one month after the second vaccine dose.

Protection of trial subjects:

Subjects that did not meet inclusion and exclusion criteria were not vaccinated. Vaccinations were performed by qualified and trained study personnel.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	17 May 2010
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	France: 163
Country: Number of subjects enrolled	Germany: 196
Country: Number of subjects enrolled	Canada: 121
Worldwide total number of subjects	480
EEA total number of subjects	359

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)	480
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 480 subjects were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2202083A Group

Arm description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of GSK2202083A vaccine, co-administered with Prevenar 13 at 2, 4 and 12 months of age. The GSK2202083A and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	Biological: GSK2202083A vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses given at 2, 4 and 12 months of age

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

Dosage and administration details:

3 co-administered doses

Investigational medicinal product name	Biological: Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Oral, two doses

Arm title	Infanrix hexa Group

Arm description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of Infanrix hexa vaccine, co-administered with Prevenar 13 and Menjugate at 2, 4 and 12 months of age. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and upper left sides of the thigh, respectively and the Menjugate vaccine was administered intramuscularly in the lower left thigh. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Biological: Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 co-administered doses	
Investigational medicinal product name	Biological: Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 doses given at 2, 4 and 12 months of age	
Investigational medicinal product name	Biological: Menjugate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 co-administered doses	
Investigational medicinal product name	Biological: Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use
Dosage and administration details: Oral, two doses	

Number of subjects in period 1	GSK2202083A Group	Infanrix hexa Group
Started	238	242
Completed	225	228
Not completed	13	14
Consent withdrawn by subject	1	2
Protocol Violation	2	-
Unspecified	2	4
Eligibility Criteria	-	1
Lost to follow-up	7	7
Non serious AEs	1	-

Baseline characteristics

Reporting groups

Reporting group title	GSK2202083A Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of GSK2202083A vaccine, co-administered with Prevenar 13 at 2, 4 and 12 months of age. The GSK2202083A and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of Infanrix hexa vaccine, co-administered with Prevenar 13 and Menjugate at 2, 4 and 12 months of age. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and upper left sides of the thigh, respectively and the Menjugate vaccine was administered intramuscularly in the lower left thigh. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Reporting group values	GSK2202083A Group	Infanrix hexa Group	Total
Number of subjects	238	242	480
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: weeks			
arithmetic mean	9.1	9.2	
standard deviation	± 1.15	± 1.17	-
Gender categorical Units: Subjects			
Female	108	111	219
Male	130	131	261
Race/Ethnicity Units: Subjects			
African heritage/African American	2	3	5
American Indian or Alaskan Native	2	0	2
Asian-Central/South Asian heritage	1	1	2
Asian-East Asian heritage	5	1	6
Asian-South East Asian heritage	2	1	3
White-Arabic/North African heritage	5	8	13
White-Caucasian/European heritage	210	216	426
Unspecified	11	12	23

End points

End points reporting groups

Reporting group title	GSK2202083A Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of GSK2202083A vaccine, co-administered with Prevenar 13 at 2, 4 and 12 months of age. The GSK2202083A and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of Infanrix hexa vaccine, co-administered with Prevenar 13 and Menjugate at 2, 4 and 12 months of age. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and upper left sides of the thigh, respectively and the Menjugate vaccine was administered intramuscularly in the lower left thigh. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Primary: Number of subjects with anti-polyribosylribitol phosphate (anti-PRP) above the cut-offs.

End point title	Number of subjects with anti-polyribosylribitol phosphate (anti-PRP) above the cut-offs.[1]

End point description:

The anti-PRP antibody concentrations cut-off was ≥ 0.15 and ≥ 1.0 micrograms per milliliter (µg/mL). The results for Month 3 ≥ 0.15 µg/mL were the primary efficacy variables.

End point type	Primary

End point timeframe:

At Month 3, Month 10 and Month 11.

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 scope of this primary end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	223		
Units: Subjects				
Anti-PRP at Month 3 ≥ 0.15 [N=216;223]	204	188		
Anti-PRP at Month 10 ≥ 0.15 [N=197;195]	145	123		
Anti-PRP at Month 11 ≥ 0.15 [N=200;196]	200	196		
Anti-PRP at Month 3 ≥ 1.0 [N=216;223]	134	82		
Anti-PRP at Month 10 ≥ 1.0 [N=197;195]	32	26		
Anti-PRP at Month 11 ≥ 1.0 [N=200;196]	198	185		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Neisseria meningitidis using baby rabbit complement (rSBA-MenC) antibodies above the cut-offs.

End point title	Number of subjects with Neisseria meningitidis using baby rabbit complement (rSBA-MenC) antibodies above the cut-offs.[2]

End point description:

The rSBA-MenC cut-offs were ≥ 1:8 and ≥ 1:128. The results for Month 3 ≥ 1:8 were the primary efficacy variables.

End point type	Primary

End point timeframe:

At Month 3, Month 10 and Month 11.

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 scope of this primary end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	214	220		
Units: Subjects				
rSBA-MenC at Month 3 ≥ 1:8 [N=214;220]	210	219		
rSBA-MenC at Month 10 ≥ 1:8 [N=194;191]	178	154		
rSBA-MenC at Month 11 ≥ 1:8 [N=199;196]	198	196		
rSBA-MenC at Month 3 ≥ 1:128 [N=214;220]	201	219		
rSBA-MenC at Month 10 ≥ 1:128 [N=194;191]	119	92		
rSBA-MenC at Month 11 ≥ 1:128 [N=199;196]	192	196		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PRP.

End point title	Concentrations for anti-PRP.

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The seroprotection reference cut-off values were ≥ 0.15 µg/mL and ≥ 1.0 µg/mL.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	223		
Units: Units:µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP at Month 3 [N=216;223]	1.594 (1.306 to 1.946)	0.671 (0.548 to 0.822)		
Anti-PRP at Month 10 [N=197;195]	0.34 (0.283 to 0.407)	0.26 (0.217 to 0.311)		
Anti-PRP at Month 11 [N=200;196]	17.678 (15.058 to 20.753)	13.737 (11.205 to 16.84)		

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for rSBA-MenC.

End point title	Titers for rSBA-MenC.

End point description:

Titers were expressed as geometric mean titers (GMCs). The seropositivity reference cut-off values were ≥ 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	214	220		
Units: Units:titers				
geometric mean (confidence interval 95%)				
rSBA-MenC at Month 3 [N=214;220]	1119.5 (926.4 to 1353)	3200.5 (2737.7 to 3741.6)		
rSBA-MenC at Month 10 [N=194;191]	131.1 (105.4 to 163.1)	73.7 (56.9 to 95.3)		
rSBA-MenC at Month 11 [N=199;196]	2653.8 (2225.5 to 3164.6)	6028.4 (5183.4 to 7011.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies above the cut-off.

End point title	Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibodies above the cut-off.

End point description:

The anti-D and anti-T antibody cut-off was ≥ 0.1 international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	223		
Units: Subjects				
Anti-D at Month 3 [N=216;223]	215	222		
Anti-D at Month 10 [N=197;195]	143	169		
Anti-D at Month 11 [N=200;196]	200	196		
Anti-T at Month 3 [N=216;223]	216	223		
Anti-T at Month 10 [N=197;195]	189	176		
Anti-T at Month 11 [N=200;196]	200	196		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs). The reference cut-off value was ≥ 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	223		
Units: Units:IU/mL				
geometric mean (confidence interval 95%)				
Anti-D at Month 3 [N=216;223]	0.936 (0.825 to 1.062)	1.197 (1.069 to 1.34)		
Anti-D at Month 10 [N=197;195]	0.183 (0.159 to 0.211)	0.241 (0.211 to 0.276)		
Anti-D at Month 11 [N=200;196]	4.538 (4.127 to 4.99)	5.307 (4.862 to 5.793)		
Anti-T at Month 3 [N=216;223]	2.543 (2.332 to 2.774)	1.38 (1.245 to 1.529)		
Anti-T at Month 10 [N=197;195]	0.458 (0.407 to 0.515)	0.249 (0.219 to 0.282)		
Anti-T at Month 11 [N=200;196]	7.647 (7.063 to 8.279)	4.72 (4.281 to 5.203)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-hepatitis B (anti-HBs) antibody concentration equal to or above (≥) 10 and 100 milli-International units per milliliter (mIU/mL)

End point title	Number of subjects with anti-hepatitis B (anti-HBs) antibody concentration equal to or above (≥) 10 and 100 milli-International units per milliliter (mIU/mL)

End point description:

A decrease in the specificity of the anti-HB enzyme-linked immunosorbent assay (ELISA) had been observed in some studies for low levels of antibody (10-100 mIU/mL). All the available blood samples initially tested with ELISA were re-tested using the Chemi Luminescence Immuno Assay (CLIA) approved by the US Food and Drug Administration (FDA). The table shows updated results following partial or complete retesting/reanalysis.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	207	216		
Units: Subjects				
Anti-HBs ≥ 10 mIU/mL at Month 3 [N=207;216]	204	215		
Anti-HBs ≥ 10 mIU/mL at Month 10 [N=197;195]	182	190		
Anti-HBs ≥ 10 mIU/mL at Month 11 [N=196;196]	194	196		
Anti-HBs ≥ 100 mIU/mL at Month 3 [N=207;216]	190	207		

Anti-HBs ≥ 100 mIU/mL at Month 10 [N=197;195]	118	146		
Anti-HBs ≥ 100 mIU/mL at Month 11 [N=196;196]	187	194		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-HBs.

End point title	Concentrations for anti-HBs.

End point description:

A decrease in the specificity of the anti-HB enzyme-linked immunosorbent assay (ELISA) had been observed in some studies for low levels of antibody (10-100 mIU/mL). All the available blood samples initially tested with ELISA were re-tested using the Chemi Luminescence Immuno Assay (CLIA) approved by the US Food and Drug Administration (FDA). The table shows updated results following partial or complete retesting/reanalysis.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	207	216		
Units: Units:mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs at Month 3 [N=207;216]	701.6 (578.4 to 851.1)	897.8 (764.9 to 1053.9)		
Anti-HBs at Month 10 [N=197;195]	134.9 (107.6 to 169.2)	212.8 (176.7 to 256.2)		
Anti-HBs at Month 11 [N=196;196]	3934.7 (3121.8 to 4959.3)	4850.7 (4059 to 5796.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-poliovirus (anti-polio) types 1, 2 and 3 above the cut-off.

End point title	Number of subjects with anti-poliovirus (anti-polio) types 1, 2 and 3 above the cut-off.

End point description:

The anti-polio 1, 2 and 3 antibody concentrations cut-off value was ≥ 1:8.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	208		
Units: Subjects				
Anti-polio 1 at Month 3 [N=196;208]	168	183		
Anti-polio 1 at Month 10 [N=183;188]	82	98		
Anti-polio 1 at Month 11 [N=191;189]	182	186		
Anti-polio 2 at Month 3 [N=196;208]	159	160		
Anti-polio 2 at Month 10 [N=183;188]	87	96		
Anti-polio 2 at Month 11 [N=191;189]	188	186		
Anti-polio 3 at Month 3 [N=196;208]	169	188		
Anti-polio 3 at Month 10 [N=183;188]	96	108		
Anti-polio 3 at Month 11 [N=191;189]	188	185		

Statistical analyses

No statistical analyses for this end point

Secondary: Titers for anti-polio 1, 2 and 3.

End point title	Titers for anti-polio 1, 2 and 3.

End point description:

Titers were expressed as geometric mean titers (GMTs). The reference cut-off value was ≥ 1:8.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	208		
Units: Units:titers				
geometric mean (confidence interval 95%)				
Anti-polio 1 at Month 3 [N=196;208]	37.5 (30.1 to 46.8)	52.1 (42.1 to 64.5)		
Anti-polio 1 at Month 10 [N=183;188]	9.3 (7.8 to 10.9)	11.2 (9.4 to 13.4)		
Anti-polio 1 at Month 11 [N=191;189]	268.4 (216.5 to 332.7)	313.7 (258.7 to 380.4)		
Anti-polio 2 at Month 3 [N=196;208]	28.1 (22.6 to 35)	30.6 (24.5 to 38.2)		

Anti-polio 2 at Month 10 [N=183;188]	10 (8.4 to 11.9)	10.5 (8.8 to 12.4)		
Anti-polio 2 at Month 11 [N=191;189]	379 (311 to 461.9)	429.2 (357.6 to 515.2)		
Anti-polio 3 at Month 3 [N=196;208]	70 (54 to 90.7)	91.9 (71.8 to 117.6)		
Anti-polio 3 at Month 10 [N=183;188]	13 (10.7 to 15.9)	15.1 (12.4 to 18.4)		
Anti-polio 3 at Month 11 [N=191;189]	506.5 (407.9 to 628.9)	541.9 (443.6 to 661.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) above the cut-off.

End point title	Number subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) above the cut-off.

End point description:

The reference cut-off for anti-PT, anti-FHA and anti-PRN antibody concentrations was ≥ 5 enzyme-linked immunosorbent assay (ELISA) units per milliliters (EL.U/mL).

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	217	223		
Units: Subjects				
Anti-PT at Month 3 [N=217;223]	217	223		
Anti-PT at Month 10 [N=193;194]	136	153		
Anti-PT at Month 11 [N=200;196]	199	195		
Anti-FHA at Month 3 [N=216;222]	216	222		
Anti-FHA at Month 10 [N=197;196]	196	195		
Anti-FHA at Month 11 [N=199;196]	199	196		
Anti-PRN at Month 3 [N=217;223]	216	222		
Anti-PRN at Month 10 [N=197;196]	129	142		
Anti-PRN at Month 11 [N=200;198]	200	198		

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). The reference cut-off value was ≥ 5 EL.U/mL.

End point type	Secondary

End point timeframe:

At Month 3, Month 10 and Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	217	223		
Units: Units:EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT at Month 3 [N=217;223]	47.4 (43.3 to 51.9)	49.3 (45.6 to 53.3)		
Anti-PT at Month 10 [N=193;194]	8 (7 to 9.1)	8.3 (7.4 to 9.3)		
Anti-PT at Month 11 [N=200;196]	74.9 (67.2 to 83.5)	86.1 (77.8 to 95.4)		
Anti-FHA at Month 3 [N=216;222]	165.8 (151.5 to 181.5)	172.3 (157.9 to 188.1)		
Anti-FHA at Month 10 [N=197;196]	37.8 (33.3 to 43)	39.7 (35.3 to 44.6)		
Anti-FHA at Month 11 [N=199;196]	429.6 (388.4 to 475)	451.2 (413.7 to 492.1)		
Anti-PRN at Month 3 [N=217;223]	66.2 (56.9 to 77)	74.5 (64.7 to 85.7)		
Anti-PRN at Month 10 [N=197;196]	9.1 (7.7 to 10.8)	11 (9.3 to 13.1)		
Anti-PRN at Month 11 [N=200;198]	218 (188.5 to 252.2)	242.9 (216.1 to 273.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a booster response to anti-PT, anti-FHA and anti-PRN.

End point title	Number of subjects with a booster response to anti-PT, anti-FHA and anti-PRN.

End point description:

Booster response defined as: for initially seronegative subjects, antibody concentration ≥ 5 EL.U/mL at Month 11; for initially seropositive subjects: antibody concentration at Month 11 ≥ 2 fold the pre-vaccination antibody concentration

End point type	Secondary

End point timeframe:

At Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	193		
Units: Subjects				
Anti-FHA [N=191;190]	183	185		
Anti-PRN [N=193;193]	191	190		
Anti-PT [N=189;189]	185	186		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal (anti-PNE) serotypes above the cut-offs.

End point title	Number of subjects with anti-pneumococcal (anti-PNE) serotypes above the cut-offs.

End point description:

The anti-PNE antibody concentrations reference cut-offs were ≥ 0.2 and ≥ 0.05 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:

At Month 3 and Month 11

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	94		
Units: Subjects				
Anti-PNE 1 at Month 3 ≥ 0.2 [N=87;94]	86	94		
Anti-PNE 1 at Month 11 ≥ 0.2 [N=86;83]	86	83		
Anti-PNE 3 at Month 3 ≥ 0.2 [N=83;93]	82	93		
Anti-PNE 3 at Month 11 ≥ 0.2 [N=86;83]	83	83		
Anti-PNE 4 at Month 3 ≥ 0.2 [N=82;94]	78	93		
Anti-PNE 4 at Month 11 ≥ 0.2 [N=86;83]	85	83		
Anti-PNE 5 at Month 3 ≥ 0.2 [N=80;91]	75	89		
Anti-PNE 5 at Month 11 ≥ 0.2 [N=86;83]	86	83		
Anti-PNE 6A at Month 3 ≥ 0.2 [N=80;92]	70	86		
Anti-PNE 6A at Month 11 ≥ 0.2 [N=86;83]	84	83		

Anti-PNE 6B at Month 3 ≥ 0.2 [N=80;92]	20	27		
Anti-PNE 6B at Month 11 ≥ 0.2 [N=86;83]	83	82		
Anti-PNE 7F at Month 3 ≥ 0.2 [N=84;93]	83	93		
Anti-PNE 7F at Month 11 ≥ 0.2 [N=86;83]	86	83		
Anti-PNE 9V at Month 3 ≥ 0.2 [N=82;91]	77	89		
Anti-PNE 9V at Month 11 ≥ 0.2 [N=86;83]	85	83		
Anti-PNE 14 at Month 3 ≥ 0.2 [N=85;93]	85	92		
Anti-PNE 14 at Month 11 ≥ 0.2 [N=86;83]	86	82		
Anti-PNE 18C at Month 3 ≥ 0.2 [N=83;93]	79	89		
Anti-PNE 18C at Month 11 ≥ 0.2 [N=86;83]	86	83		
Anti-PNE 19A at Month 3 ≥ 0.2 [N=83;93]	74	91		
Anti-PNE 19A at Month 11 ≥ 0.2 [N=86;83]	85	83		
Anti-PNE 19F at Month 3 ≥ 0.2 [N=81;92]	79	92		
Anti-PNE 19F at Month 11 ≥ 0.2 [N=85;82]	84	82		
Anti-PNE 23F at Month 3 ≥ 0.2 [N=77;92]	52	76		
Anti-PNE 23F at Month 11 ≥ 0.2 [N=86;83]	84	82		
Anti-PNE 1 at Month 3 ≥ 0.05 [N=87;94]	87	94		
Anti-PNE 1 at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 3 at Month 3 ≥ 0.05 [N=83;93]	83	93		
Anti-PNE 3 at Month 11 ≥ 0.05 [N=86;83]	85	83		
Anti-PNE 4 at Month 3 ≥ 0.05 [N=82;94]	82	94		
Anti-PNE 4 at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 5 at Month 3 ≥ 0.05 [N=80;91]	79	91		
Anti-PNE 5 at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 6A at Month 3 ≥ 0.05 [N=80;92]	79	91		
Anti-PNE 6A at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 6B at Month 3 ≥ 0.05 [N=80;92]	54	72		
Anti-PNE 6B at Month 11 ≥ 0.05 [N=86;83]	85	83		
Anti-PNE 7F at Month 3 ≥ 0.05 [N=84;93]	84	93		
Anti-PNE 7F at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 9V at Month 3 ≥ 0.05 [N=82;91]	80	91		

Anti-PNE 9V at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 14 at Month 3 ≥ 0.05 [N=85;93]	85	93		
Anti-PNE 14 at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 18C at Month 3 ≥ 0.05 [N=83;93]	83	93		
Anti-PNE 18C at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 19A at Month 3 ≥ 0.05 [N=83;93]	83	93		
Anti-PNE 19A at Month 11 ≥ 0.05 [N=86;83]	86	83		
Anti-PNE 19F at Month 3 ≥ 0.05 [N=81;92]	81	92		
Anti-PNE 19F at Month 11 ≥ 0.05 [N=85;82]	85	82		
Anti-PNE 23F at Month 3 ≥ 0.05 [N=77;92]	73	89		
Anti-PNE 23F at Month 11 ≥ 0.05 [N=86;83]	85	82		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations for anti-PNE serotypes.

End point title	Concentrations for anti-PNE serotypes.

End point description:

Concentrations were expressed as geometric mean concentreations (GMCs). The reference cut-off value was ≥ 0.2 µg/mL.

End point type	Secondary

End point timeframe:

At Month 3 and Month 11

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	87	94		
Units: Units:µg/mL				
geometric mean (confidence interval 95%)				
Anti-PNE 1 at Month 3 ≥ 0.2 [N=87;94]	1.66 (1.37 to 2)	1.89 (1.59 to 2.25)		
Anti-PNE 1 at Month 11 ≥ 0.2 [N=86;83]	4.99 (4.13 to 6.02)	4.79 (4.12 to 5.56)		
Anti-PNE 3 at Month 3 ≥ 0.2 [N=83;93]	1.16 (0.99 to 1.35)	1.15 (1.02 to 1.3)		
Anti-PNE 3 at Month 11 ≥ 0.2 [N=86;83]	1.74 (1.41 to 2.16)	1.82 (1.54 to 2.15)		
Anti-PNE 4 at Month 3 ≥ 0.2 [N=82;94]	1.4 (1.14 to 1.73)	1.55 (1.32 to 1.82)		

Anti-PNE 4 at Month 11 ≥ 0.2 [N=86;83]	4.19 (3.46 to 5.06)	4.43 (3.77 to 5.21)		
Anti-PNE 5 at Month 3 ≥ 0.2 [N=80;91]	1.83 (1.38 to 2.43)	2.17 (1.76 to 2.68)		
Anti-PNE 5 at Month 11 ≥ 0.2 [N=86;83]	6.68 (5.47 to 8.17)	6.75 (5.67 to 8.02)		
Anti-PNE 6A at Month 3 ≥ 0.2 [N=80;92]	1.06 (0.82 to 1.39)	1.2 (0.98 to 1.48)		
Anti-PNE 6A at Month 11 ≥ 0.2 [N=86;83]	7.34 (5.87 to 9.16)	7.96 (6.95 to 9.11)		
Anti-PNE 6B at Month 3 ≥ 0.2 [N=80;92]	0.09 (0.07 to 0.12)	0.12 (0.09 to 0.15)		
Anti-PNE 6B at Month 11 ≥ 0.2 [N=86;83]	2.23 (1.68 to 2.97)	2.78 (2.23 to 3.46)		
Anti-PNE 7F at Month 3 ≥ 0.2 [N=84;93]	2.72 (2.3 to 3.21)	2.75 (2.44 to 3.1)		
Anti-PNE 7F at Month 11 ≥ 0.2 [N=86;83]	6.67 (5.82 to 7.65)	6.47 (5.68 to 7.38)		
Anti-PNE 9V at Month 3 ≥ 0.2 [N=82;91]	1.36 (1.02 to 1.82)	1.42 (1.17 to 1.74)		
Anti-PNE 9V at Month 11 ≥ 0.2 [N=86;83]	6.12 (4.99 to 7.5)	6.8 (5.78 to 8)		
Anti-PNE 14 at Month 3 ≥ 0.2 [N=85;93]	3.03 (2.42 to 3.8)	2.96 (2.33 to 3.76)		
Anti-PNE 14 at Month 11 ≥ 0.2 [N=86;83]	10.41 (8.56 to 12.65)	7.5 (6.03 to 9.34)		
Anti-PNE 18C at Month 3 ≥ 0.2 [N=83;93]	1.81 (1.4 to 2.34)	2.08 (1.72 to 2.51)		
Anti-PNE 18C at Month 11 ≥ 0.2 [N=86;83]	6.2 (5.06 to 7.59)	5.91 (4.97 to 7.02)		
Anti-PNE 19A at Month 3 ≥ 0.2 [N=83;93]	1.05 (0.81 to 1.36)	1.3 (1.1 to 1.54)		
Anti-PNE 19A at Month 11 ≥ 0.2 [N=86;83]	5.73 (4.55 to 7.2)	5.22 (4.26 to 6.41)		
Anti-PNE 19F at Month 3 ≥ 0.2 [N=81;92]	2.82 (2.25 to 3.53)	3.36 (2.83 to 3.98)		
Anti-PNE 19F at Month 11 ≥ 0.2 [N=85;82]	5.47 (4.36 to 6.86)	5.7 (4.81 to 6.75)		
Anti-PNE 23F at Month 3 ≥ 0.2 [N=77;92]	0.4 (0.29 to 0.54)	0.54 (0.43 to 0.68)		
Anti-PNE 23F at Month 11 ≥ 0.2 [N=86;83]	4.38 (3.33 to 5.77)	4.51 (3.57 to 5.69)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PRP and rSBA-MenC fold increase distribution.

End point title	Number of subjects with anti-PRP and rSBA-MenC fold increase distribution.

End point description:

The fold increase distribution cut-offs were: ≥2, ≥4, ≥6, ≥8 and ≥10.

End point type	Secondary

End point timeframe:

At Month 11.

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	197	193		
Units: Subjects				
Anti-PRP ≥2 [N=197;193]	195	189		
Anti-PRP ≥4 [N=197;193]	191	186		
Anti-PRP ≥6 [N=197;193]	189	176		
Anti-PRP ≥8 [N=197;193]	179	170		
Anti-PRP ≥10 [N=197;193]	173	166		
rSBA-MenC ≥2 [N=193;189]	189	185		
rSBA-MenC ≥4 [N=193;189]	177	185		
rSBA-MenC ≥6 [N=193;189]	160	182		
rSBA-MenC ≥8 [N=193;189]	148	180		
rSBA-MenC ≥10 [N=193;189]	135	178		

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 8-day (Days 0-7) post-vaccination period

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238	241		
Units: Subjects				
Any pain	155	181		
Any redness	171	183		
Any swelling	147	163		

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 8-day (Days 0-7) post-vaccination period

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238	241		
Units: Subjects				
Any drowsiness	188	190		
Any irritability	208	207		
Any loss of appetite	169	154		
Any fever	165	167		

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

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238	242		
Units: Subjects				
Any AEs	148	158		

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 (Month 0 to Month 11)

End point values	GSK2202083A Group	Infanrix hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	238	242		
Units: Subjects				
Any SAEs	12	15		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: 8-day (Days 0-7) follow-up period after vaccination; unsolicited AEs: 31-day (Days 0-30) follow-up period after vaccination; SAEs: during the entire study period (Months 0-11).

Adverse event reporting additional description:

For solicited local and general symptoms, the number of participants at risk included those from Total Vaccinated cohort who had the symptom sheet completed. 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	14

Reporting groups

Reporting group title	GSK2202083A Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of GSK2202083A vaccine, co-administered with Prevenar 13 at 2, 4 and 12 months of age. The GSK2202083A and Prevenar 13 vaccines were administered intramuscularly into the right and left sides of the thigh, respectively. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects aged between and including 8 and 12 weeks of age at the time of first vaccination received 3 doses of Infanrix hexa vaccine, co-administered with Prevenar 13 and Menjugate at 2, 4 and 12 months of age. The Infanrix hexa and Prevenar 13 vaccines were administered intramuscularly into the right and upper left sides of the thigh, respectively and the Menjugate vaccine was administered intramuscularly in the lower left thigh. An optional 2-dose vaccination with Rotarix was offered to the study participants at 2 and 4 months of age.

Serious adverse events	GSK2202083A Group	Infanrix hexa Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 238 (5.04%)	15 / 242 (6.20%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Concussion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	3 / 242 (1.24%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Accidental drug intake by child			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Tremor			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenopathy			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Crying			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Sandifer’s syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Apnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Choking			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			

Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis adenovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 238 (0.00%)	1 / 242 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Metabolism and nutrition disorders			
Cow's milk intolerance			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 242 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	GSK2202083A Group	Infanrix hexa Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	232 / 238 (97.48%)	237 / 242 (97.93%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed[1]	155 / 238 (65.13%)	181 / 241 (75.10%)	
occurrences (all)	155	181	
Redness			
subjects affected / exposed[2]	171 / 238 (71.85%)	183 / 241 (75.93%)	
occurrences (all)	171	183	
Swelling			
subjects affected / exposed[3]	147 / 238 (61.76%)	163 / 241 (67.63%)	
occurrences (all)	147	163	
Drowsiness			
subjects affected / exposed[4]	188 / 238 (78.99%)	190 / 241 (78.84%)	
occurrences (all)	188	190	
Irritability			
subjects affected / exposed[5]	208 / 238 (87.39%)	207 / 241 (85.89%)	
occurrences (all)	208	207	
Loss of appetite			
subjects affected / exposed[6]	169 / 238 (71.01%)	154 / 241 (63.90%)	
occurrences (all)	169	154	
Temperature			
subjects affected / exposed[7]	165 / 238 (69.33%)	167 / 241 (69.29%)	
occurrences (all)	165	167	
Gastrointestinal disorders			

Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 238 (5.04%)	17 / 242 (7.02%)	
occurrences (all)	12	17	
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 238 (3.78%)	14 / 242 (5.79%)	
occurrences (all)	9	14	
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	19 / 238 (7.98%)	14 / 242 (5.79%)	
occurrences (all)	19	14	
Infections and infestations			
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	31 / 238 (13.03%)	27 / 242 (11.16%)	
occurrences (all)	31	27	
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	20 / 238 (8.40%)	15 / 242 (6.20%)	
occurrences (all)	20	15	
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	10 / 238 (4.20%)	16 / 242 (6.61%)	
occurrences (all)	10	16	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This solicited local symptom was only collected from subjects with their symptom sheets completed.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This solicited local symptom was only collected from subjects with their symptom sheets completed.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This solicited local symptom was only collected from subjects with their symptom sheets completed.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: This solicited general symptom was only collected from subjects with their symptom sheets completed.

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

Justification: This solicited general symptom was only collected from subjects with their symptom sheets completed.

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

Justification: This solicited general symptom was only collected from subjects with their symptom sheets completed.

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

Justification: This solicited general symptom was only collected from subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 January 2010	After the approval of Prevenar 13, it was recommended to use this one instead of Prevenar 7 according to the same vaccination schedule at 2, 4 and 12 months of age . Additionally, contraindications to the administration of Rotarix were added to the exclusion criteria.
06 April 2010	GSK Biologicals has identified the presence of material from PCV-1 in its Human Rotavirus vaccine (444563). PCV-1 is a well known virus that does not replicate in humans and is not known to cause illness in humans. GSK's Vaccine Safety Monitoring Board has reviewed all data and has concluded that the benefit/risk profile of the vaccine remains unchanged and is favourable. However the subject informed consent form has been updated to include information about this finding, since it might affect the willingness of a subject's parent / Legally Acceptable Representative (s) (LAR) to allow their child to participate or continue participation in the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported