Clinical trial results:
A Phase III, randomized, open-label, controlled, multicenter study to evaluate immunogenicity and safety of GSK Biologicals' Infanrix hexa vaccine when administered to healthy infants as primary vaccination at 2, 4 and 6 months of age, co-administered with Prevnar and Rotarix with a booster dose of GSK Biologicals' Infanrix and Hiberix vaccines at 15-18 months of age.

Summary

EudraCT number	2013-004304-19
Trial protocol	Outside EU/EEA
Global end of trial date	13 November 2015

Results information

Result version number	v1 (current)
This version publication date	22 July 2018
First version publication date	22 July 2018

Trial information

Trial identification

Sponsor protocol code	117119

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02096263
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 Cente, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Cente, 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	05 April 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 November 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of Infanrix hexa to Pediarix co-administered with ActHIB, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigens [pertussis toxoid (PT), filamentous hemagglutinin (FHA) and pertactin (PRN)] one month after the third dose of the primary vaccination.

Protection of trial subjects:

The subjects were observed closely for at least 30 minutes following the administration of the vaccines, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 2014
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	United States: 585
Worldwide total number of subjects	585
EEA total number of subjects	0

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)	585
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:

This study was conducted in 43 centers in the United States of America (USA).

Pre-assignment

Screening details:

All subjects enrolled were included in the trial.

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	Infanrix hexa Group

Arm description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Infanrix hexa (lot A, lot B or lot C as per the group allocation) co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and Hiberix at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Arm type	Experimental
Investigational medicinal product name	Infanrix hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as a booster dose at 15-18 months of age.

Investigational medicinal product name	Hiberix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as a booster dose at 15-18 months of age.

Investigational medicinal product name	Prevnar13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

This vaccine was administered as 2 doses at 2 and 4 months of age.

Arm title	Pediarix Group

Arm description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pediarix and ActHIB co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and ActHIB at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Arm type	Active comparator
Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as a booster dose at 15-18 months of age.

Investigational medicinal product name	Prevnar13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

This vaccine was administered as 2 doses at 2 and 4 months of age.

Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 primary doses at 2, 4 and 6 months of age and as a booster dose at

15-18 months of age.

Arm title	Pentacel Group

Arm description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pentacel and Engerix co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Pentacel at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Arm type	Active comparator
Investigational medicinal product name	Engerix-B
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Prevnar13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 doses at 2, 4 and 6 months of age.

Investigational medicinal product name	Rotarix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for oral suspension
Routes of administration	Oral use

Dosage and administration details:

This vaccine was administered as 2 doses at 2 and 4 months of age.

Investigational medicinal product name	Pentacel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

This vaccine was administered as 3 primary doses at 2, 4 and 6 months of age and as a booster dose at 15 to 18 months of age.

Number of subjects in period 1	Infanrix hexa Group	Pediarix Group	Pentacel Group
Started	195	194	196
Completed	161	158	157
Not completed	34	36	39
Consent withdrawn by subject	5	7	8
Sponsor study termination	-	-	1
Adverse event, non-fatal	1	-	1
Unspecified	7	9	6
Lost to follow-up	14	18	15
Protocol deviation	7	2	8

Baseline characteristics

Reporting groups

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Infanrix hexa (lot A, lot B or lot C as per the group allocation) co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and Hiberix at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pediarix Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pediarix and ActHIB co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and ActHIB at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pentacel Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pentacel and Engerix co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Pentacel at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group values	Infanrix hexa Group	Pediarix Group	Pentacel Group
Number of subjects	195	194	196
Age categorical Units: Subjects			
Age continuous Units: weeks			
arithmetic mean	8.5	8.6	8.6
standard deviation	± 1.0	± 1.1	± 1.1
Gender categorical Units: Subjects			
Male	94	114	101
Female	101	80	95
Race/Ethnicity, Customized Units: Subjects			
Asian - Japanese Heritage	1	0	1
African Heritage / African American	16	9	20
Asian - East Asian Heritage	3	2	0
White - Caucasian / European Heritage	118	128	115
Asian - Central/South Asian Heritage	2	2	1
White - Arabic / North African Heritage	0	1	0
Unspecified	29	27	32

American Indian or Alaskan Native	15	15	17
Native Hawaiian or Other Pacific Islander	2	1	2
Asian - South East Asian Heritage	9	9	8

Reporting group values	Total		
Number of subjects	585		
Age categorical Units: Subjects			

Age continuous Units: weeks			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Male	309		
Female	276		
Race/Ethnicity, Customized Units: Subjects			
Asian - Japanese Heritage	2		
African Heritage / African American	45		
Asian - East Asian Heritage	5		
White - Caucasian / European Heritage	361		
Asian - Central/South Asian Heritage	5		
White - Arabic / North African Heritage	1		
Unspecified	88		
American Indian or Alaskan Native	47		
Native Hawaiian or Other Pacific Islander	5		
Asian - South East Asian Heritage	26		

End points

End points reporting groups

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Infanrix hexa (lot A, lot B or lot C as per the group allocation) co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and Hiberix at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pediarix Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pediarix and ActHIB co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and ActHIB at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pentacel Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pentacel and Engerix co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Pentacel at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Primary: Antibody concentrations for pertussis toxoid (Anti-PT), filamentous hemagglutinin (Anti-FHA) and pertactin (Anti-PRN).

End point title	Antibody concentrations for pertussis toxoid (Anti-PT), filamentous hemagglutinin (Anti-FHA) and pertactin (Anti-PRN).

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs) for the following cut-offs:2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN. The results for the Infanrix hexa Group and Pediarix Group were the primary outcome variables.

End point type	Primary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	149	149	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-PT	43.2 (38.1 to 48.9)	48.3 (42.7 to 54.5)	24.2 (21.1 to 27.7)	
Anti-FHA	106.3 (95.0 to 119.0)	122.7 (109.9 to 137.0)	59.9 (51.7 to 69.3)	

Anti-PRN	57.4 (49.5 to 66.6)	46.9 (39.9 to 55.3)	33.0 (27.8 to 39.1)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

To demonstrate the non-inferiority of Infanrix hexa to Pediarix co-administered with ActHIB, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigen, pertussis toxoid (PT), one month after the third dose of the primary vaccination.

Comparison groups	Infanrix hexa Group v Pediarix Group
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.31

Notes:

[1] - Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pediarix Group divided by Infanrix hexa Group] is ≤ 1.5.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

To demonstrate the non-inferiority of Infanrix hexa to Pediarix co-administered with ActHIB, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigen, filamentous hemagglutinin (FHA), one month after the third dose of the primary vaccination.

Comparison groups	Infanrix hexa Group v Pediarix Group
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.35

Notes:

[2] - Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pediarix Group divided by Infanrix hexa Group] is ≤ 1.5.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

To demonstrate the non-inferiority of Infanrix hexa to Pediarix co-administered with ActHIB, in terms of antibody geometric mean concentrations (GMCs) for pertussis antigen, pertactin (PRN), one month after the third dose of the primary vaccination.

Comparison groups	Infanrix hexa Group v Pediarix Group
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.99

Notes:

[3] - Non-inferiority in terms of immune response to pertussis antigens will be demonstrated if, for each of the three antigens, the upper limit of the 95% confidence interval (CI) on the GMC ratio [Pediarix Group divided by Infanrix hexa Group] is ≤ 1.5.

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

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

End point description:

A seropositve subject was defined as a subject with antibody concentrations above to or equal to (≥) 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	149	149	
Units: Participants				
Anti-PT	146	148	148	
Anti-FHA	146	149	149	
Anti-PRN	146	148	148	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against diphtheria (D) and tetanus (T).

End point title	Number of seroprotected subjects against diphtheria (D) and tetanus (T).

End point description:

A seroprotected subject was defined a a subject with antibody concentrations ≥ 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	149	149	
Units: Participants				
Anti-T (N=146;149;149)	146	149	148	
Anti-D (N=142;144;149)	142	144	149	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for Anti-D and Anti-T.

End point title	Antibody concentrations for Anti-D and Anti-T.

End point description:

Concentrations were expressed as GMCs for the seroprotection cut-off of 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	146	149	149	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-T (N=146;149;149)	2.458 (2.195 to 2.753)	2.633 (2.338 to 2.966)	2.012 (1.768 to 2.290)	
Anti-D (N=142;144;149)	1.777 (1.551 to 2.036)	1.648 (1.44 to 1.886)	1.249 (1.095 to 1.425)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-polio types 1, 2 and 3.	
End point title	Number of seroprotected subjects against anti-polio types 1, 2 and 3.
End point description:	
A seroprotected subject was defined as a subject with anti-polio types 1, 2 and 3 titres ≥ 8 dilution.	
End point type	Secondary
End point timeframe:	
At Month 5, one month after the third dose of the primary vaccination	

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	137	134	136	
Units: Participants				
Anti-polio 1 (N=137;134;136)	137	134	135	
Anti-polio 2 (N=133;131;134)	133	131	134	
Anti-polio 3 (N=129;132;126)	129	132	124	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titres for anti-polio types 1, 2 and 3.	
End point title	Antibody titres for anti-polio types 1, 2 and 3.
End point description:	
Titres were expressed as geometric mean titres (GMTs) for the cut-off of 8 dilution.	
End point type	Secondary
End point timeframe:	
At Month 5, one month after the third dose of the primary vaccination	

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	137	134	136	
Units: titres				
geometric mean (confidence interval 95%)				
Anti-polio 1 (N=137;134;1136)	546.9 (447.7 to 668.0)	604.1 (495.9 to 736.0)	319.5 (256.8 to 397.5)	
Anti-polio 2 (N=133;131;134)	483.5 (394.2 to 593.0)	567.7 (448.8 to 718.1)	283.0 (229.4 to 349.2)	
Anti-polio 3 (N=129;132;126)	722.2 (577.4 to 903.4)	927.0 (740.7 to 1160.3)	294.6 (221.6 to 391.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against polyribosyl ribitol phosphate (Anti-PRP).

End point title	Number of seroprotected subjects against polyribosyl ribitol phosphate (Anti-PRP).

End point description:

A seroprotected subject was defined as a subject with anti-PRP concentrations ≥ 0.15 µg/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	154	156	
Units: Participants				
Participants	146	151	154	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-PRP antibody concentrations ≥ 1 µg/mL.

End point title	Number of subjects with Anti-PRP antibody concentrations ≥ 1 µg/mL.

End point description:

The cut-off for this assay was an anti-PRP concentration ≥ 1 µg/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	154	156	
Units: Participants				
Participants	85	145	130	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for Anti-PRP.

End point title	Antibody concentrations for Anti-PRP.

End point description:

Antibody concentrations were expressed as GMCs for the assay cut-off of 1 µg/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	154	156	
Units: µg/mL				
geometric mean (confidence interval 95%)				
µg/mL	1.348 (1.076 to 1.688)	9.258 (7.362 to 11.642)	5.717 (4.363 to 7.492)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against hepatitis B (Anti-HBs).

End point title	Number of seroprotected subjects against hepatitis B (Anti-HBs).

End point description:

A seroprotected subject was defined as a subject with anti-HBs antibody concentrations ≥ 10 mIU/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134	138	136	
Units: Participants				
Participants	134	138	133	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for Anti-HBs.

End point title	Antibody concentrations for Anti-HBs.

End point description:

Antibody concentrations were expressed as GMCs for the seroprotection cut-off of 10 mIU/mL.

End point type	Secondary

End point timeframe:

At Month 5, one month after the third dose of the primary vaccination

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134	138	136	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	2258.8 (1910.7 to 2670.4)	1886.0 (1565.6 to 2271.9)	1053.4 (780.2 to 1422.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

The solicited local symptoms assessed were pain, redness and swelling. Any = any reports of the specific symptom irrespective of intensity grade; above or equal (≥); Grade 2 Redness/Swelling: > 5 millimeters (mm); Grade 3 Redness/Swelling: > 20 mm; Grade 2 Pain = Moderate: cries/protests on touch; Grade 3 Pain = Severe: Cries when limb is moved/spontaneously painful. Grade = G; Medical Advice = MA; Inf hexa = Infanrix hexa, Ped = Pediarix, Pen = Pentacel. Subjects in Infanrix hexa Group did not receive the ActHIB or Engerix vaccines.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 1

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	185	189	188	
Units: Participants				
Any Pain, ActHIB/Engerix (N=0;189;188)	0	123	100	
≥ G 2 Pain, ActHIB/Engerix (N=0;189;188)	0	66	45	
G 3 Pain, ActHIB/Engerix (N=0;189;188)	0	22	10	
MA Pain, ActHIB/Engerix (N=0;189;188)	0	1	0	
Any Pain, Inf hexa/Ped/Pen (N=185;189;188)	94	113	115	
≥ G 2 Pain, Inf hexa/Ped/Pen (N=185;189;188)	40	65	51	
G 3 Pain, Inf hexa/Ped/Pen (N=185;189;188)	8	17	12	
MA Pain, Inf hexa/Ped/Pen (N=185;189;188)	1	0	0	
Any Redness, ActHIB/Engerix (N=0;189;188)	0	63	55	
≥ G 2 Redness, ActHIB/Engerix (N=0;189;188)	0	19	12	
G 3 Redness, ActHIB/Engerix (N=0;189;188)	0	8	1	
MA Redness, ActHIB/Engerix (N=0;189;188)	0	1	0	
Any Redness, Inf hexa/Ped/Pen (N=185;189;188)	47	56	57	
≥ G 2 Redness, Inf hexa/Ped/Pen (N=185;189;188)	15	15	20	
G 3 Redness,Inf hexa/Ped/Pen (N=185;189;188)	3	4	3	
MA Redness, Inf hexa/Ped/Pen (N=185;189;188)	0	0	0	
Any Swelling, ActHIB/Engerix (N=0;189;188)	0	41	39	
≥ G 2 Swelling, ActHIB/Engerix (N=0;189;188)	0	14	14	
G 3 Swelling, ActHIB/Engerix (N=0;189;188)	0	6	3	
MA Swelling, ActHIB/Engerix (N=0;189;188)	0	1	0	
Any Swelling, Inf hexa/Ped/Pen (N=185;189;188)	31	35	45	
≥ G 2 Swelling, Inf hexa/Ped/Pen (N=185;189;188)	10	14	24	
G 3 Swelling, Inf hexa/Ped/Pen (N=185;189;188)	2	3	11	
MA Swelling, Inf hexa/Ped/Pen (N=185;189;188)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

The solicited local symptoms assessed were pain, redness (Red) and swelling (Swe). Any = any reports of the specific symptom irrespective of intensity grade; above or equal (≥); Grade 2 Redness/Swelling: > 5 millimeters (mm); Grade 3 Redness/Swelling: > 20 mm; Grade 2 Pain = Moderate: cries/protests on touch; Grade 3 Pain = Severe: Cries when limb is moved/spontaneously painful. Grade = G; Medical Advice = MA; Inf hexa = Infanrix hexa, Ped = Pediarix, Pen = Pentacel. Subjects in Infanrix hexa Group did not receive the ActHIB or Engerix vaccines.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 2

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	182	184	180	
Units: Participants				
Any Pain, ActHIB/Engerix (N=0;184;13)	0	104	6	
≥ G 2 Pain, ActHIB/Engerix (N=0;184;13)	0	47	2	
G 3 Pain, ActHIB/Engerix (N=0;184;13)	0	9	0	
MA Pain, ActHIB/Engerix (N=0;184;13)	0	0	0	
Any Pain, Inf hexa/Ped/Pen (N=182;184;180)	84	108	93	
≥G2 Pain, Inf hexa/Ped/Pen (N=182;184;180)	25	44	31	
G3 Pain, Inf hexa/Ped/Pen (N=182;184;180)	1	7	6	
MA Pain, Inf hexa/Ped/Pen (N=182;184;180)	0	0	0	
Any Redness, ActHIB/Engerix (N=0;184;13)	0	66	5	
≥ G 2 Redness, ActHIB/Engerix (N=0;184;13)	0	17	1	
G 3 Redness, ActHIB/Engerix (N=0;184;13)	0	1	0	
MA Redness, ActHIB/Engerix (N=0;184;13)	0	0	0	
Any Red, Inf hexa/Ped/Pen (N=182;184;180)	59	61	64	
≥G2 Red,Inf hexa/Ped/Pen (N=182;184;180)	15	12	15	
G 3 Red, Inf hexa/Ped/Pen (N=182;184;180)	3	3	2	
MA Red, Inf hexa/Ped/Pen (N=182;184;180)	0	0	0	
Any Swelling, ActHIB/Engerix (N=0;184;13)	0	40	3	
≥ G 2 Swelling, ActHIB/Engerix (N=0;184;13)	0	11	0	

G 3 Swelling, ActHIB/Engerix (N=0;184;13)	0	1	0	
MA Swelling, ActHIB/Engerix (N=0;184;13)	0	0	0	
Any Swe, Inf hexa/Ped/Pen (N=182;184;180)	41	40	42	
≥G2 Swe, Inf hexa/Ped/Pen (N=182;184;180)	10	12	7	
G 3 Swe, Inf hexa/Ped/Pen (N=182;184;180)	2	2	3	
MA Swe, Inf hexa/Ped/Pen (N=182;184;180)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

The solicited local symptoms assessed were pain, redness and swelling. Any = any reports of the specific symptom irrespective of intensity grade; above or equal (≥); Grade 2 Redness/Swelling: > 5 millimeters (mm); Grade 3 Redness (Red)/Swelling (Swe): > 20 mm; Grade 2 Pain = Moderate: cries/protests on touch; Grade 3 Pain = Severe: Cries when limb is moved/spontaneously painful. Grade = G; Medical Advice = MA; Inf hexa = Infanrix hexa, Ped = Pediarix, Pen = Pentacel. Subjects in Infanrix hexa Group did not receive the ActHIB or Engerix vaccines.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 3

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	175	171	
Units: Participants				
Any Pain, ActHIB/Engerix (N=0;175;169)	0	93	75	
≥ G 2 Pain, ActHIB/Engerix (N=0;175;169)	0	41	25	
G 3 Pain, ActHIB/Engerix (N=0;175;169)	0	7	5	
MA Pain, ActHIB/Engerix (N=0;175;169)	0	1	0	
Any Pain, Inf hexa/Ped/Pen (N=172;175;170)	67	90	76	
≥ G2 Pain, Inf hexa/Ped/Pen (N=172;175;170)	18	39	20	
G3 Pain, Inf hexa/Ped/Pen (N=172;175;170)	0	7	7	
MA Pain, Inf hexa/Ped/Pen (N=172;175;170)	0	1	0	
Any Red, ActHIB/Engerix (N=0;175;169)	0	69	51	

≥ G 2 Red, ActHIB/Engerix (N=0;175;169)	0	7	9	
G 3 Red, ActHIB/Engerix (N=0;175;169)	0	1	2	
MA Red, ActHIB/Engerix (N=0;175;169)	0	0	0	
Any Red, Inf hexa/Ped/Pen (N=172;175;170)	63	66	56	
≥G2 Red, Inf hexa/Ped/Pen (N=172;175;170)	7	12	11	
G3 Red, Inf hexa/Ped/Pen (N=172;175;170)	1	3	0	
MA Red, Inf hexa/Ped/Pen (N=172;175;170)	0	1	0	
Any Swe, ActHIB/Engerix (N=0;175;169)	0	42	37	
≥ G 2 Swe, ActHIB/Engerix (N=0;175;169)	0	7	7	
G 3 Swe, ActHIB/Engerix (N=0;175;169)	0	1	0	
MA Swe, ActHIB/Engerix (N=0;175;169)	0	0	0	
Any Swe, Inf hexa/Ped/Pen (N=172;175;170)	43	44	35	
≥ G2 Swe, Inf hexa/Ped/Pen (N=172;175;170)	7	10	4	
G3 Swe, Inf hexa/Ped/Pen (N=172;175;170)	1	3	0	
MA Swe, Inf hexa/Ped/Pen (N=172;175;170)	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

The solicited local symptoms assessed were pain, redness and swelling. Any = any reports of the specific symptom irrespective of intensity grade; above or equal (≥); Grade 2 Redness (Red)/Swelling (Swe): > 5 millimeters (mm); Grade 3 Redness/Swelling: > 20 mm; Grade 2 Pain = Moderate: cries/protests on touch; Grade 3 Pain = Severe: Cries when limb is moved/spontaneously painful. Grade = G; Medical Advice = MA; Inf hexa = Infanrix hexa, Ped = Pediarix, Pen = Pentacel. Subjects in Infanrix hexa Group did not receive the ActHIB or Engerix vaccines.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following any dose.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	187	189	188	
Units: Participants				
Any Pain, ActHIB/Engerix (N=0;189;188)	0	148	127	
≥ G 2 Pain, ActHIB/Engerix (N=0;189;188)	0	96	62	
G 3 Pain, ActHIB/Engerix (N=0;189;188)	0	30	14	
MA Pain, ActHIB/Engerix (N=0;189;188)	0	2	0	
Any Pain, Inf hexa/Ped/Pen (N=187;189;188)	127	151	147	
≥ G2 Pain,Inf hexa/Ped/Pen (N=187;189;188)	58	93	80	
G3 Pain, Inf hexa/Ped/Pen (N=187;189;188)	8	27	22	
MA Pain, Inf hexa/Ped/Pen (N=187;189;188)	1	1	0	
Any Red, ActHIB/Engerix (N=0;189;188)	0	108	77	
≥ G 2 Red, ActHIB/Engerix (N=0;189;188)	0	38	20	
G 3 Red, ActHIB/Engerix (N=0;189;188)	0	10	3	
MA Red, ActHIB/Engerix (N=0;189;188)	0	1	0	
Any Red, Inf hexa/Ped/Pen (N=187;189;188)	94	98	87	
≥ G2 Red, Inf hexa/Ped/Pen (N=187;189;188)	27	32	37	
G3 Red, Inf hexa/Ped/Pen (N=187;189;188)	7	9	5	
MA Red, Inf hexa/Ped/Pen (N=187;189;188)	0	1	0	
Any Swe, ActHIB/Engerix (N=0;189;188)	0	78	64	
≥ G 2 Swe, ActHIB/Engerix (N=0;189;188)	0	25	18	
G 3 Swe, ActHIB/Engerix (N=0;189;188)	0	7	3	
MA Swe, ActHIB/Engerix (N=0;189;188)	0	1	0	
Any Swe, Inf hexa/Ped/Pen (N=187;189;188)	73	70	72	
≥ G2 Swe, Inf hexa/Ped/Pen (N=187;189;188)	20	26	26	
G3 Swe, Inf hexa/Ped/Pen (N=187;189;188)	4	7	12	
MA Swe, Inf hexa/Ped/Pen (N=187;189;188)	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

The solicited general symptoms assessed were Drowsiness, Irritability/Fussiness, Loss Of Appetite and Fever (defined as temperature ≥ 38.0°C). Any = any reports of the specific symptom irrespective of intensity grade; Grade 2 (G2) Drowsiness = Drowsiness that interfered with normal activity; Grade 2 Irritability/Fussiness = Moderate: Cried more than usual/interfered with normal activity; Grade 2 Loss of appetite = Ate less than usual/interfered with normal activity; Grade 2 Fever: > 39.0 °C; Grade 3 (G3) Drowsiness/Irritability/Fussiness = symptom that prevented normal activity; Grade 3 Loss of appetite = Did not eat at all; Grade 3 Fever: > 40.0 °C; Related (Rel) = Symptom which was assessed by the investigator as related to vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 1.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	185	189	188	
Units: Participants				
Any Drowsiness	114	143	149	
≥ G 2 Drowsiness	36	56	53	
G 3 Drowsiness	3	8	12	
Rel Drowsiness	112	136	141	
G3 Rel Drowsiness	3	7	12	
MA Drowsiness	1	0	0	
Any Irritability / Fussiness	115	165	153	
≥ G 2 Irritability / Fussiness	42	79	68	
G 3 Irritability / Fussiness	9	17	15	
Rel Irritability / Fussiness	113	163	147	
G3 Rel Irritability / Fussiness	9	17	15	
MA Irritability / Fussiness	1	0	0	
Any Loss of appetite	53	76	80	
≥ G 2 Loss of appetite	8	13	26	
G 3 Loss of appetite	0	1	4	
Rel Loss of appetite	48	73	77	
G3 Rel Loss of appetite	0	1	4	
MA Loss of appetite	0	0	0	
Any Fever	22	34	29	
≥ G 2 Fever	0	0	2	
G 3 Fever	0	0	0	
Rel Fever	15	31	27	
G3 Rel Fever	0	0	0	
MA Fever	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

The solicited general symptoms assessed were Drowsiness, Irritability/Fussiness, Loss Of Appetite and Fever (defined as temperature ≥ 38.0°C). Any = any reports of the specific symptom irrespective of intensity grade; Grade 2 (G2) Drowsiness = Drowsiness that interfered with normal activity; Grade 2 Irritability/Fussiness = Moderate: Cried more than usual/interfered with normal activity; Grade 2 Loss of appetite = Ate less than usual/interfered with normal activity; Grade 2 Fever: > 39.0 °C; Grade 3 (G3) Drowsiness/Irritability/Fussiness = symptom that prevented normal activity; Grade 3 Loss of appetite = Did not eat at all; Grade 3 Fever: > 40.0 °C; Related (Rel) = Symptom which was assessed by the investigator as related to vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 2.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	182	184	179	
Units: Participants				
Any Drowsiness	97	132	109	
≥ G 2 Drowsiness	31	43	39	
G 3 Drowsiness	8	7	4	
Rel Drowsiness	94	126	108	
G3 Rel Drowsiness	7	7	3	
MA Drowsiness	0	0	0	
Any Irritability / Fussiness	128	147	136	
≥ G 2 Irritability / Fussiness	53	70	61	
G 3 Irritability / Fussiness	6	14	11	
Rel Irritability / Fussiness	125	143	133	
G3 Rel Irritability / Fussiness	6	13	11	
MA Irritability / Fussiness	0	0	2	
Any Loss of appetite	56	55	56	
≥ G 2 Loss of appetite	17	15	15	
G 3 Loss of appetite	1	1	2	
Rel Loss of appetite	52	51	55	
G3 Rel Loss of appetite	1	1	2	
MA Loss of appetite	0	0	1	
Any Fever	47	36	35	
≥ G 2 Fever	2	3	2	
G 3 Fever	0	0	0	
Rel Fever	37	32	33	
G3 Rel Fever	0	0	0	
MA Fever	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

The solicited general symptoms assessed were Drowsiness, Irritability/Fussiness, Loss Of Appetite and Fever (defined as temperature ≥ 38.0°C). Any = any reports of the specific symptom irrespective of intensity grade; Grade 2 (G2) Drowsiness = Drowsiness that interfered with normal activity; Grade 2 Irritability/Fussiness = Moderate: Cried more than usual/interfered with normal activity; Grade 2 Loss of appetite = Ate less than usual/interfered with normal activity; Grade 2 Feve:r > 39.0 °C; Grade 3 (G3) Drowsiness/Irritability/Fussiness = symptom that prevented normal activity; Grade 3 Loss of appetite = Did not eat at all; Grade 3 Fever: > 40.0 °C; Related (Rel) = Symptom which was assessed by the investigator as related to vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following Dose 3.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	175	170	
Units: Participants				
Any Drowsiness	85	108	88	
≥ G 2 Drowsiness	23	37	25	
G 3 Drowsiness	3	5	9	
Rel Drowsiness	81	105	86	
G3 Rel Drowsiness	3	5	9	
MA Drowsiness	0	2	1	
Any Irritability / Fussiness	126	135	122	
≥ G 2 Irritability / Fussiness	46	58	58	
G 3 Irritability / Fussiness	6	15	11	
Rel Irritability / Fussiness	121	129	120	
G3 Rel Irritability / Fussiness	6	13	11	
MA Irritability / Fussiness	0	3	1	
Any Loss of appetite	45	58	53	
≥ G 2 Loss of appetite	11	13	15	
G 3 Loss of appetite	1	2	2	
Rel Loss of appetite	44	56	52	
G3 Rel Loss of appetite	1	2	2	
MA Loss of appetite	0	1	0	
Any Fever	40	45	37	
≥ G 2 Fever	4	11	7	
G 3 Fever	0	2	0	
Rel Fever	35	39	35	
G3 Rel Fever	0	2	0	
MA Fever	1	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

The solicited general symptoms assessed were Drowsiness, Irritability/Fussiness, Loss Of Appetite and Fever (defined as temperature ≥ 38.0°C). Any = any reports of the specific symptom irrespective of intensity grade; Grade 2 (G2) Drowsiness = Drowsiness that interfered with normal activity; Grade 2 Irritability/Fussiness = Moderate: Cried more than usual/interfered with normal activity; Grade 2 Loss of appetite = Ate less than usual/interfered with normal activity; Grade 2 Fever: > 39.0 °C; Grade 3 (G3) Drowsiness/Irritability/Fussiness = symptom that prevented normal activity; Grade 3 Loss of appetite = Did not eat at all; Grade 3 Fever: > 40.0 °C; Related (Rel) = Symptom which was assessed by the investigator as related to vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following any dose.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	187	189	188	
Units: Participants				
Any Drowsiness	147	172	168	
≥ G 2 Drowsiness	67	88	81	
G 3 Drowsiness	11	19	22	
Rel Drowsiness	144	169	166	
G3 Rel Drowsiness	11	18	21	
MA Drowsiness	1	2	1	
Any Irritability / Fussiness	164	182	177	
≥ G 2 Irritability / Fussiness	96	128	120	
G 3 Irritability / Fussiness	18	35	30	
Rel Irritability / Fussiness	161	180	175	
G3 Rel Irritability / Fussiness	18	34	30	
MA Irritability / Fussiness	1	3	3	
Any Loss of appetite	95	111	117	
≥ G 2 Loss of appetite	28	32	39	
G 3 Loss of appetite	2	3	6	
Rel Loss of appetite	91	108	116	
G3 Rel Loss of appetite	2	3	6	
MA Loss of appetite	0	1	1	
Any Fever	72	78	72	
≥ G 2 Fever	6	14	10	
G 3 Fever	0	2	0	
Rel Fever	61	74	69	
G3 Rel Fever	0	2	0	
MA Fever	1	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with specific adverse events (AEs).

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

End point description:

Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies)

End point type	Secondary

End point timeframe:

From Month 0 up to 6 months post primary-vaccination (Month 10)

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	195	194	196	
Units: Participants				
Participants	7	11	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs.

End point title	Number of subjects with unsolicited AEs.

End point description:

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

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) post-primary vaccination period.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	195	194	196	
Units: Participants				
Participants	113	108	96	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SAEs were defined as medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Secondary

End point timeframe:

From Month 0 up to 6 months post-primary vaccination (Month 10)

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	195	194	196	
Units: Participants				
Participants	7	1	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Anti-D and Anti-T.

End point title	Number of seroprotected subjects against Anti-D and Anti-T.

End point description:

A seroprotected subject was defined a subject with antibody concentrations ≥ 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)] and at Visit 6 (At Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	136	126	
Units: Participants				
Anti-T at Visit 5 (N=131;132;121)	118	123	107	
Anti-T at Visit 6 (N=138;136;126)	138	136	125	
Anti-D at Visit 5 (N=131;132;121)	128	123	115	
Anti-D at Visit 6 (N=138;136;126)	138	136	126	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for Anti-D and Anti-T.

End point title	Antibody concentrations for Anti-D and Anti-T.

End point description:

Concentrations were expressed as GMCs for the seropositivity cut-off of 0.1 IU/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [At Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	136	126	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-T at Visit 5 (N=131;132;121)	0.327 (0.281 to 0.380)	0.402 (0.340 to 0.474)	0.340 (0.281 to 0.410)	
Anti-T at Visit 6 (N=138;136;126)	9.212 (7.863 to 10.793)	8.870 (7.668 to 10.261)	6.880 (5.905 to 8.015)	
Anti-D at Visit 5 (N=131;132;121)	0.701 (0.597 to 0.825)	0.622 (0.514 to 0.753)	0.764 (0.629 to 0.928)	
Anti-D at Visit 6 (N=138;136;126)	8.334 (7.479 to 9.286)	7.886 (6.972 to 8.92)	8.537 (7.524 to 9.687)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

A seropositve subject was defined as a subject with antibody concentrations above to or equal to (≥) 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

At Visit 5 [Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	136	126	
Units: Participants				
Anti-PT at Visit 5 (N=131;132;121)	107	114	63	
Anti-FHA at Visit 5 (N=131;132;121)	130	130	113	
Anti-PRN at Visit 5 (N=131;132;120)	110	104	91	
Anti-PT at Visit 6 (N=138;136;126)	138	136	126	
Anti-FHA at Visit 6 (N=138;136;126)	138	136	126	
Anti-PRN at Visit 6 (N=137;136;125)	136	136	124	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for Anti-PT, Anti-FHA and Anti-PRN.

End point title	Antibody concentrations for Anti-PT, Anti-FHA and Anti-PRN.

End point description:

Concentrations were expressed as geometric mean concentrations (GMCs) for the following cut-offs:2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

At Visit 5 [Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	136	126	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-PT Visit 5 (N=131;132;121)	5.3 (4.6 to 6.2)	6.5 (5.6 to 7.7)	3.1 (2.6 to 3.7)	
Anti-FHA Visit 5 (N=131;132;121)	17.1 (14.7 to 19.9)	21.8 (18.3 to 26.1)	8.1 (6.6 to 9.9)	
Anti-PRN Visit 5 (N=131;132;120)	6.8 (5.5 to 8.3)	5.5 (4.5 to 6.6)	6.0 (4.8 to 7.5)	
Anti-PT Visit 6 (N=138;136;126)	71.4 (62.6 to 81.5)	87.6 (76.6 to 100.2)	55.5 (47.4 to 65.1)	
Anti-FHA Visit 6 (N=138;136;126)	186.9 (165.1 to 211.5)	250.4 (220.4 to 284.6)	101.0 (86.2 to 118.3)	
Anti-PRN Visit 6 (N=137;136;125)	208.0 (172.3 to 251.1)	215.6 (176.1 to 263.8)	130.5 (105.9 to 160.9)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Booster response to PT, FHA and PRN antigens was defined as: - For subjects with pre-vaccination antibody concentration below the assay cut off, post-vaccination antibody concentration = 4 times the assay cut-off, - For subjects with pre-vaccination antibody concentration between the assay cut off and below 4 times the assay cut-off, post-vaccination antibody concentration equal or above 4 times the pre-vaccination antibody concentration. The assay cut off is 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA, and 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

At Visit 6 [At Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	131	130	116	
Units: Participants				
Anti-PT (N=131;130;116)	126	121	111	
Anti-FHA (N=131;130;116)	130	127	114	
Anti-PRN (N=130;130;115)	128	128	112	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Anti-PRP.

End point title	Number of seroprotected subjects against Anti-PRP.

End point description:

A seroprotected subject was defined as a subject with anti-PRP concentrations ≥ 0.15 µg/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [At Month 14-17 one month after the booster dose (Dose4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	139	131	
Units: Participants				
Anti-PRP at Visit 5 (N=131;132;121)	91	122	94	
Anti-PRP at Visit 6 (N=138;139;131)	138	139	129	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-PRP antibody concentrations ≥ 1 µg/mL.

End point title	Number of subjects with Anti-PRP antibody concentrations ≥ 1 µg/mL.

End point description:

The cut-off for this assay was an anti-PRP concentration ≥ 1 µg/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [At Month 14-17 one month after the booster dose (Dose4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	139	131	
Units: Participants				
Anti-PRP at Visit 5 (N=131;132;121)	23	71	47	
Anti-PRP at Visit 6 (N=138;139;131)	136	138	128	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for anti-PRP.

End point title	Antibody concentrations for anti-PRP.

End point description:

Antibody concentrations were expressed as GMCs for the seroprotection cut-off of 1 µg/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)] and at Visit 6 [At Month 14-17 one month after the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	138	139	131	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP at Visit 5 (N=131;132;121)	0.301 (0.242 to 0.373)	0.987 (0.775 to 1.256)	0.614 (0.458 to 0.822)	
Anti-PRP at Visit 6 (N=138;139;131)	39.365 (31.520 to 49.164)	51.140 (41.954 to 62.339)	27.318 (21.140 to 35.302)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against anti-polio types 1, 2 and 3.

End point title	Number of seroprotected subjects against anti-polio types 1, 2 and 3.

End point description:

A seroprotected subject was defined as a subject with anti-polio types 1, 2 and 3 titres ≥ 8 dilution.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	128	129	117	
Units: Participants				
Anti-polio 1 (N=128;128;116)	124	121	100	
Anti-polio 2 (N=128;128;117)	119	122	109	
Anti-polio 3 (N=127;129;117)	123	126	80	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titres for anti-polio types 1, 2 and 3.

End point title	Antibody titres for anti-polio types 1, 2 and 3.

End point description:

Titres were expressed as geometric mean titres (GMTs) for the cut-off of 8 dilution.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	128	129	117	
Units: titres				
geometric mean (confidence interval 95%)				
Anti-polio 1 (N=128;128;116)	99.5 (79.4 to 124.8)	107.4 (83.7 to 137.9)	42.2 (32.6 to 54.6)	
Anti-polio 2 (N=128;128;117)	94.9 (73.2 to 123.1)	111.9 (88.0 to 142.4)	51.2 (40.8 to 64.3)	
Anti-polio 3 (N=127;129;117)	122.1 (95.1 to 156.9)	160.4 (125.8 to 204.6)	28.4 (20.6 to 39.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Anti-HBs.

End point title	Number of seroprotected subjects against Anti-HBs.

End point description:

A seroprotected subject was defined as a subject with anti-HBs antibody concentrations ≥ 10 mIU/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	133	131	121	
Units: Participants				
Participants	131	128	105	

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations for anti-HBs.

End point title	Antibody concentrations for anti-HBs.

End point description:

Antibody concentrations were expressed as GMCs for the seroprotection cut-off of 10 mIU/mL.

End point type	Secondary

End point timeframe:

At Visit 5 [At Month 13-16 before the booster dose (Dose 4)]

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	133	131	121	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
mIU/mL	328.7 (261.5 to 413.2)	235.8 (188.2 to 295.5)	149.4 (100.5 to 222.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.

End point description:

The solicited local symptoms assessed were pain, redness and swelling. Any = any reports of the specific symptom irrespective of intensity grade; above or equal (≥); Grade 2 Redness (Red)/Swelling (Swe): > 5 millimeters (mm); Grade 3 Redness/Swelling: > 20 mm; Grade 2 Pain = Moderate: cries/protests on touch; Grade 3 Pain = Severe: Cries when limb is moved/spontaneously painful. Grade = G; Medical Advice = MA. Subjects in Pentacel Group did not receive the ActHIB or Hiberix vaccines.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-booster vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	154	151	150	
Units: Participants				
Any Pain, ActHIB/Hiberix (N=153;151;0)	61	64	0	
≥ G 2 Pain, ActHIB/Hiberix (N=153;151;0)	11	15	0	
G 3 Pain, ActHIB/Hiberix (N=153;151;0)	1	2	0	
MA Pain, ActHIB/Hiberix (N=153;151;0)	0	0	0	
Any Pain, Infanrix/Pentacel (N=154;151;150)	62	74	59	
≥ G2 Pain, Infanrix/Pentacel (N=154;151;150)	12	19	16	
G3 Pain, Infanrix/Pentacel (N=154;151;150)	2	3	2	

MA Pain, Infanrix/Pentacel (N=154;151;150)	1	0	0	
Any Red, ActHIB/Hiberix (N=153;151;0)	42	49	0	
≥ G 2 Red, ActHIB/Hiberix (N=153;151;0)	7	4	0	
G 3 Red, ActHIB/Hiberix (N=153;151;0)	0	2	0	
MA Red, ActHIB/Hiberix (N=153;151;0)	0	0	0	
Any Red, Infanrix/Pentacel (N=154;151;150)	49	60	47	
≥ G2 Red, Infanrix/Pentacel (N=154;151;150)	17	14	13	
G3 Red, Infanrix/Pentacel (N=154;151;150)	8	4	2	
MA Red, Infanrix/Pentacel (N=154;151;150)	2	0	0	
Any Swe, ActHIB/Hiberix (N=153;151;0)	29	29	0	
≥ G 2 Swe, ActHIB/Hiberix (N=153;151;0)	7	6	0	
G 3 Swe, ActHIB/Hiberix (N=153;151;0)	0	2	0	
MA Swe, ActHIB/Hiberix (N=153;151;0)	0	0	0	
Any Swe, Infanrix/Pentacel (N=154;151;150)	42	44	35	
≥ G2 Swe, Infanrix/Pentacel (N=154;151;150)	13	17	14	
G3 Swe, Infanrix/Pentacel (N=154;151;150)	5	7	4	
MA Swe, Infanrix/Pentacel (N=154;151;150)	2	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.

End point description:

The solicited general symptoms assessed were Drowsiness, Irritability/Fussiness, Loss Of Appetite and Fever (defined as temperature ≥ 38.0°C). Any = any reports of the specific symptom irrespective of intensity grade; Grade 2 (G2) Drowsiness = Drowsiness that interfered with normal activity; Grade 2 Irritability/Fussiness = Moderate: Cried more than usual/interfered with normal activity; Grade 2 Loss of appetite = Ate less than usual/interfered with normal activity; Grade 2 Fever: > 39.0 °C and ≤ 40.0 °C; Grade 3 (G3) Drowsiness/Irritability/Fussiness = symptom that prevented normal activity; Grade 3 Loss of appetite = Did not eat at all; Grade 3 Fever: > 40.0 °C; Related (Rel) = Symptom which was assessed by the investigator as related to vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-booster vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	153	150	151	
Units: Participants				
Any Drowsiness	59	67	65	
≥ G 2 Drowsiness	18	20	17	
G 3 Drowsiness	1	3	2	
Rel Drowsiness	55	65	61	
G3 Rel Drowsiness	1	3	2	
MA Drowsiness	0	0	0	
Any Irritability / Fussiness	86	94	76	
≥ G 2 Irritability / Fussiness	26	35	23	
G 3 Irritability / Fussiness	3	4	4	
Rel Irritability / Fussiness	85	92	68	
G3 Rel Irritability / Fussiness	3	4	4	
MA Irritability / Fussiness	0	0	1	
Any Loss of appetite	47	47	46	
≥ G 2 Loss of appetite	8	9	11	
G 3 Loss of appetite	1	2	2	
Rel Loss of appetite	44	44	41	
G3 Rel Loss of appetite	1	2	2	
MA Loss of appetite	0	0	0	
Any Fever	4	10	11	
≥ G 2 Fever	1	1	1	
G 3 Fever	0	0	0	
Rel Fever	2	10	9	
G3 Rel Fever	0	0	0	
MA Fever	0	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with specific AEs.

End point title	Number of subjects with specific AEs.

End point description:

Occurrence of specific adverse events, i.e., new onset chronic diseases (e.g. autoimmune disorders, asthma, type I diabetes and allergies)

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) post-booster vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	158	161	
Units: Participants				
Participants	4	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs.

End point title	Number of subjects with unsolicited AEs.

End point description:

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

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) post-booster vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	158	161	
Units: Participants				
Participants	37	35	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs.

End point title	Number of subjects with SAEs.

End point description:

SAEs were defined as medical occurrences that resulted in death, were life threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity.

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) post-booster vaccination.

End point values	Infanrix hexa Group	Pediarix Group	Pentacel Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	158	161	
Units: Participants				
Participants	1	0	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 4-day (Day 0-Day 3) follow-up period after each dose. Unsolicited AEs: during the 31-day (Day 0-Day 30) follow-up period after each dose. SAEs: during the entire study period (from Month 0 to Month 17).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Infanrix hexa Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Infanrix hexa (lot A, lot B or lot C as per the group allocation) co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and Hiberix at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pediarix Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pediarix and ActHIB co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Infanrix and ActHIB at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Reporting group title	Pentacel Group

Reporting group description:

Subjects between, and including, 6 and 12 weeks of age at the time of the vaccination received, in the Primary Phase of the study, 3 doses of Pentacel and Engerix co-administered with Prevnar13 at 2, 4 and 6 months of age and Rotarix at 2 and 4 months of age. The injectable vaccines were administered by intramuscular injection in the anterolateral thigh, while Rotarix was administered orally. Subjects received a booster dose of Pentacel at 15-18 months of age by intramuscular injection in the anterolateral thigh.

Serious adverse events	Infanrix hexa Group	Pediarix Group	Pentacel Group
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 195 (4.10%)	1 / 194 (0.52%)	8 / 196 (4.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Near drowning			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Road traffic accident			

subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Seizure like phenomena			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Respiratory, thoracic and mediastinal disorders			
Apparent life threatening event			

subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choking			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Hypoxia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Respiratory distress			
subjects affected / exposed	3 / 195 (1.54%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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

Parainfluenzae virus infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	2 / 196 (1.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Infanrix hexa Group	Pediarix Group	Pentacel Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	188 / 195 (96.41%)	190 / 194 (97.94%)	187 / 196 (95.41%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Haemangioma			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Crying			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Ill-defined disorder			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	2 / 195 (1.03%)	2 / 194 (1.03%)	5 / 196 (2.55%)
occurrences (all)	2	2	5
Injection site erythema			
subjects affected / exposed	112 / 195 (57.44%)	129 / 194 (66.49%)	116 / 196 (59.18%)
occurrences (all)	228	299	248
Injection site induration			
subjects affected / exposed	3 / 195 (1.54%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	4	1	0
Injection site mass			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	0	2	0
Injection site nodule			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	141 / 195 (72.31%)	162 / 194 (83.51%)	152 / 196 (77.55%)
occurrences (all)	322	423	361
Injection site pruritus			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Injection site rash			

subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	2 / 196 (1.02%)
occurrences (all)	1	0	3
Injection site scab			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	92 / 195 (47.18%)	103 / 194 (53.09%)	90 / 196 (45.92%)
occurrences (all)	166	201	180
Injection site warmth			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	0	2	0
Oedema peripheral			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 195 (0.00%)	3 / 194 (1.55%)	0 / 196 (0.00%)
occurrences (all)	0	3	0
Pyrexia			
subjects affected / exposed	82 / 195 (42.05%)	85 / 194 (43.81%)	82 / 196 (41.84%)
occurrences (all)	133	136	130
Swelling			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Vaccination site bruising			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	1 / 196 (0.51%)
occurrences (all)	0	3	1
Vaccination site erythema			
subjects affected / exposed	2 / 195 (1.03%)	5 / 194 (2.58%)	3 / 196 (1.53%)
occurrences (all)	2	5	3
Vaccination site induration			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	3 / 196 (1.53%)
occurrences (all)	2	1	3
Vaccination site swelling			

subjects affected / exposed	3 / 195 (1.54%)	1 / 194 (0.52%)	2 / 196 (1.02%)
occurrences (all)	3	1	2
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Food allergy			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	0	1	1
Milk allergy			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	3 / 195 (1.54%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	3	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	2 / 195 (1.03%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	2	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	0	2	0
Penile adhesion			
subjects affected / exposed	3 / 195 (1.54%)	3 / 194 (1.55%)	0 / 196 (0.00%)
occurrences (all)	3	3	0
Penile erythema			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	3 / 196 (1.53%)
occurrences (all)	0	0	3
Bronchial hyperreactivity			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	2	1	0
Cough			

subjects affected / exposed	17 / 195 (8.72%)	8 / 194 (4.12%)	7 / 196 (3.57%)
occurrences (all)	20	8	7
Dysphonia			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	3 / 195 (1.54%)	6 / 194 (3.09%)	2 / 196 (1.02%)
occurrences (all)	3	7	2
Respiratory arrest			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Respiratory disorder			
subjects affected / exposed	1 / 195 (0.51%)	2 / 194 (1.03%)	1 / 196 (0.51%)
occurrences (all)	1	2	1
Rhinitis allergic			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	1	1	1
Rhinorrhoea			
subjects affected / exposed	5 / 195 (2.56%)	4 / 194 (2.06%)	5 / 196 (2.55%)
occurrences (all)	5	5	6
Sinus congestion			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract congestion			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Wheezing			
subjects affected / exposed	2 / 195 (1.03%)	0 / 194 (0.00%)	3 / 196 (1.53%)
occurrences (all)	3	0	3
Psychiatric disorders			

Irritability			
subjects affected / exposed	167 / 195 (85.64%)	183 / 194 (94.33%)	180 / 196 (91.84%)
occurrences (all)	461	544	488
Screaming			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Investigations			
Body temperature increased			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Cardiac murmur			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	2	1	1
Arthropod sting			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Clavicle fracture			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Concussion			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Contusion			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Corneal abrasion			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Craniocerebral injury			

subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Foreign body			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	0	1	1
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	1 / 196 (0.51%)
occurrences (all)	0	2	1
Head injury			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	3 / 196 (1.53%)
occurrences (all)	1	0	3
Mouth injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Nasal injury			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Thermal burn			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Congenital, familial and genetic disorders			
Congenital skin dimples			
subjects affected / exposed	0 / 195 (0.00%)	3 / 194 (1.55%)	1 / 196 (0.51%)
occurrences (all)	0	3	1
Dacryostenosis congenital			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Dermoid cyst			

subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Hydrocele			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Hypospadias			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	0	2	0
Macrocephaly			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	2	1	0
Phimosis			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Plagiocephaly			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Cyanosis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	2 / 196 (1.02%)
occurrences (all)	0	0	2
Nervous system disorders			
Hyperreflexia			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Poor quality sleep			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	152 / 195 (77.95%)	173 / 194 (89.18%)	173 / 196 (88.27%)
occurrences (all)	355	450	411
Speech disorder developmental			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Tremor			

subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	2	1	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	2 / 196 (1.02%)
occurrences (all)	0	1	2
Ear disorder			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Ear pain			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	2 / 196 (1.02%)
occurrences (all)	0	0	2
Tympanic membrane perforation			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Anal fistula			

subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 195 (0.51%)	2 / 194 (1.03%)	5 / 196 (2.55%)
occurrences (all)	1	3	5
Diarrhoea			
subjects affected / exposed	6 / 195 (3.08%)	7 / 194 (3.61%)	13 / 196 (6.63%)
occurrences (all)	7	7	14
Flatulence			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Frequent bowel movements			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 195 (0.00%)	8 / 194 (4.12%)	1 / 196 (0.51%)
occurrences (all)	0	8	1
Inguinal hernia			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Teething			
subjects affected / exposed	8 / 195 (4.10%)	10 / 194 (5.15%)	11 / 196 (5.61%)
occurrences (all)	10	11	12
Vomiting			
subjects affected / exposed	13 / 195 (6.67%)	10 / 194 (5.15%)	12 / 196 (6.12%)
occurrences (all)	13	11	12
Vomiting projectile			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Dermatitis			
subjects affected / exposed	4 / 195 (2.05%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	4	1	0
Dermatitis atopic			
subjects affected / exposed	5 / 195 (2.56%)	8 / 194 (4.12%)	7 / 196 (3.57%)
occurrences (all)	5	8	7
Dermatitis contact			
subjects affected / exposed	2 / 195 (1.03%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	2	2	0
Dermatitis diaper			
subjects affected / exposed	4 / 195 (2.05%)	4 / 194 (2.06%)	10 / 196 (5.10%)
occurrences (all)	4	4	11
Dry skin			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Eczema			
subjects affected / exposed	5 / 195 (2.56%)	5 / 194 (2.58%)	4 / 196 (2.04%)
occurrences (all)	5	5	4
Erythema			
subjects affected / exposed	0 / 195 (0.00%)	3 / 194 (1.55%)	0 / 196 (0.00%)
occurrences (all)	0	3	0
Hair growth abnormal			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Hypertrichosis			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Post inflammatory pigmentation change			

subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	6 / 195 (3.08%)	8 / 194 (4.12%)	6 / 196 (3.06%)
occurrences (all)	6	8	6
Rash erythematous			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Rash generalised			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Seborrhoea			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	1	1	1
Seborrhoeic dermatitis			
subjects affected / exposed	3 / 195 (1.54%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	3	1	0
Urticaria			
subjects affected / exposed	0 / 195 (0.00%)	3 / 194 (1.55%)	0 / 196 (0.00%)
occurrences (all)	0	3	0
Renal and urinary disorders			
Urethral meatus stenosis			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Asymmetric gluteal fold			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	2 / 195 (1.03%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	2	0	1
Positional plagiocephaly			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Anal abscess			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	3 / 195 (1.54%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	3	0	1
Bronchitis			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Candida infection			
subjects affected / exposed	2 / 195 (1.03%)	2 / 194 (1.03%)	0 / 196 (0.00%)
occurrences (all)	2	2	0
Candida nappy rash			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	1	1	1
Conjunctivitis			
subjects affected / exposed	10 / 195 (5.13%)	9 / 194 (4.64%)	1 / 196 (0.51%)
occurrences (all)	10	10	1
Conjunctivitis bacterial			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	0	1	1
Conjunctivitis viral			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1

Croup infectious			
subjects affected / exposed	2 / 195 (1.03%)	2 / 194 (1.03%)	2 / 196 (1.02%)
occurrences (all)	2	2	2
Ear infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Eczema herpeticum			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Exanthema subitum			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Eye infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Folliculitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	1 / 195 (0.51%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	1	1	0
Gastric infection			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	2 / 195 (1.03%)	2 / 194 (1.03%)	1 / 196 (0.51%)
occurrences (all)	2	2	1
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 195 (0.51%)	2 / 194 (1.03%)	2 / 196 (1.02%)
occurrences (all)	1	2	2
Herpangina			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	2	0	1

Hordeolum			
subjects affected / exposed	2 / 195 (1.03%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	2	1	1
Impetigo			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	2 / 196 (1.02%)
occurrences (all)	1	0	3
Influenza			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	4 / 195 (2.05%)	1 / 194 (0.52%)	4 / 196 (2.04%)
occurrences (all)	5	1	4
Oral candidiasis			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	1 / 196 (0.51%)
occurrences (all)	0	1	1
Otitis externa			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	10 / 195 (5.13%)	11 / 194 (5.67%)	12 / 196 (6.12%)
occurrences (all)	10	13	12
Otitis media acute			
subjects affected / exposed	2 / 195 (1.03%)	3 / 194 (1.55%)	0 / 196 (0.00%)
occurrences (all)	2	3	0
Otitis media chronic			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Pertussis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	2	0	1
Pneumonia			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0

Respiratory syncytial virus infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	3 / 196 (1.53%)
occurrences (all)	0	0	3
Roseola			
subjects affected / exposed	0 / 195 (0.00%)	1 / 194 (0.52%)	0 / 196 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Skin candida			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	1	0	1
Staphylococcal infection			
subjects affected / exposed	1 / 195 (0.51%)	0 / 194 (0.00%)	0 / 196 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	32 / 195 (16.41%)	26 / 194 (13.40%)	32 / 196 (16.33%)
occurrences (all)	35	31	35
Urinary tract infection			
subjects affected / exposed	0 / 195 (0.00%)	2 / 194 (1.03%)	1 / 196 (0.51%)
occurrences (all)	0	2	1
Viraemia			
subjects affected / exposed	0 / 195 (0.00%)	0 / 194 (0.00%)	1 / 196 (0.51%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	4 / 195 (2.05%)	3 / 194 (1.55%)	8 / 196 (4.08%)
occurrences (all)	4	3	8
Viral rash			
subjects affected / exposed	3 / 195 (1.54%)	0 / 194 (0.00%)	4 / 196 (2.04%)
occurrences (all)	3	0	4

Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 195 (0.00%) 0	0 / 194 (0.00%) 0	3 / 196 (1.53%) 3
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	112 / 195 (57.44%) 201	126 / 194 (64.95%) 236	127 / 196 (64.80%) 235

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported