Clinical trial results:
A phase III, partially double-blind clinical trial to evaluate the immunogenicity and reactogenicity of GlaxoSmithKline (GSK) Biologicals' combined Infanrix hexa vaccine (new formulation) as compared with GSK Biologicals' combined Infanrix hexa vaccine (current formulation) administered in healthy infants at 3, 4 and 5 months of age. The immunogenicity, safety and reactogenicity of the DTPa-HBV-IPV vaccine will also be evaluated in a third group of subjects.

Summary

EudraCT number	2012-002427-15
Trial protocol	Outside EU/EEA
Global end of trial date	25 January 2007

Results information

Result version number	v1 (current)
This version publication date	11 May 2016
First version publication date	25 June 2015

Trial information

Trial identification

Sponsor protocol code	105910

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00320463
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 June 2007
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 January 2007
Global end of trial reached?	Yes
Global end of trial date	25 January 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 2006
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	Russian Federation: 417
Worldwide total number of subjects	417
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)	417
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The study was double-blind with respect to the 2 Infanrix Hexa Groups and single-blind with respect to the Infanrix Penta Group. Infanrix ™ Hexa vaccine (preservative-containing) was used as a control in this study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Infanrix Hexa NEW Group

Arm description:

Subjects who received the preservative-free formulation of the Infanrix hexa vaccine

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

Dosage and administration details:

Three doses of vaccine were administered intramuscularly into the anterolateral quadrant of the right tight at 3, 4 and 5 months of age.

Arm title	Infanrix Hexa REF Group

Arm description:

Subjects who received the preservative-containing formulation of the Infanrix hexa vaccine

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

Dosage and administration details:

Three doses of vaccine were administered intramuscularly into the anterolateral quadrant of the right tight at 3, 4 and 5 months of age.

Arm title	Infanrix Penta Group

Arm description: -

Arm type	Experimental

Investigational medicinal product name	Infanrix™ penta
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of vaccine were administered intramuscularly into the anterolateral quadrant of the right tight at 3, 4 and 5 months of age.

Number of subjects in period 1	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group
Started	167	167	83
Completed	163	165	82
Not completed	4	2	1
Consent withdrawn by subject	2	1	1
Migrated/moved from study area	1	1	-
Unspecified	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Infanrix Hexa NEW Group
Reporting group description:	
Subjects who received the preservative-free formulation of the Infanrix hexa vaccine	
Reporting group title	Infanrix Hexa REF Group
Reporting group description:	
Subjects who received the preservative-containing formulation of the Infanrix hexa vaccine	
Reporting group title	Infanrix Penta Group
Reporting group description: -	

Reporting group values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group
Number of subjects	167	167	83
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: weeks			
arithmetic mean	12.9	13	12.9
standard deviation	± 1.27	± 1.32	± 1.28
Gender categorical Units: Subjects			
Female	79	69	51
Male	88	98	32

Reporting group values	Total		
Number of subjects	417		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		

85 years and over	0		

Age continuous Units: weeks arithmetic mean standard deviation	- 		
Gender categorical Units: Subjects			
Female	199		
Male	218		

End points

End points reporting groups

Reporting group title	Infanrix Hexa NEW Group
Reporting group description: Subjects who received the preservative-free formulation of the Infanrix hexa vaccine	
Reporting group title	Infanrix Hexa REF Group
Reporting group description: Subjects who received the preservative-containing formulation of the Infanrix hexa vaccine	
Reporting group title	Infanrix Penta Group
Reporting group description: -	

Primary: Number of seroprotected subjects against Hepatitis B (anti-HBS) antigen with cut off value of 10 mIU/mL

End point title	Number of seroprotected subjects against Hepatitis B (anti-HBS) antigen with cut off value of 10 mIU/mL
End point description:	
End point type	Primary
End point timeframe: At one month after (POST) Dose 3	

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	123	63	
Units: Subjects				
Anti-HBs, POST (N=116,123,63)	115	121	61	

Statistical analyses

Statistical analysis title	Difference in seroprotection rates for anti-HBs
Statistical analysis description: To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.	
Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	239
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference in seroprotection rate
Point estimate	-0.76

Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.97
upper limit	3.24

Notes:

[1] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

Primary: Number of seroprotected subjects against polyribosyl ribitol phosphate (anti-PRP) antigen with cut off value of 0.15 µg/mL

End point title	Number of seroprotected subjects against polyribosyl ribitol phosphate (anti-PRP) antigen with cut off value of 0.15 µg/mL

End point description:

End point type	Primary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	106	54	
Units: Subjects				
Anti-PRP, POST (N=104,106,54)	98	102	12	

Statistical analyses

Statistical analysis title	Difference in seroprotection rates for anti-PRP

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in seroprotection rate
Point estimate	2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.31
upper limit	8.74

Notes:

[2] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

Primary: Number of seroprotected subjects against diphtheria (anti-D) and tetanus (anti-T) antigen with cut off value of 0.1 IU/mL.	
End point title	Number of seroprotected subjects against diphtheria (anti-D) and tetanus (anti-T) antigen with cut off value of 0.1 IU/mL.

End point description:

End point type	Primary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	106	54	
Units: Subjects				
Anti-D, POST (N=104,106,54)	101	102	52	
Anti-T, POST (N=104,106,54)	103	106	54	

Statistical analyses

Statistical analysis title	Difference in seroprotection rates for Anti-D

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in seroprotection rate
Point estimate	-0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	4.84

Notes:

[3] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

Statistical analysis title	Difference in seroprotection rates for Anti-T

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	210
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in seroprotection rate
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.55
upper limit	5.25

Primary: Number of seroprotected subjects against Poliomyelitis (anti-Polio 1, anti Polio2, Anti-Polio 3) antigen with cut off value of 8.

End point title	Number of seroprotected subjects against Poliomyelitis (anti-Polio 1, anti Polio2, Anti-Polio 3) antigen with cut off value of 8.

End point description:

End point type	Primary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	74	37	
Units: Subjects				
Anti-Polio1, POST (N=60,66,31)	60	66	31	
Anti-Polio2, POST (N=64,74,36)	64	74	36	
Anti-Polio3, POST (N=71,72,37)	71	72	37	

Statistical analyses

Statistical analysis title	Seroprotection rates difference for anti-Polio 1

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group

Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in seroprotection rate
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	6.02

Notes:

[4] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

Statistical analysis title	Seroprotection rates difference for anti-Polio 2

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in seroprotection rate
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.93
upper limit	5.66

Notes:

[5] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

Statistical analysis title	Seroprotection rates difference for anti-Polio 3

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	145
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference in seroprotection rate
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.07
upper limit	5.13

Notes:

[6] - The upper limit of the standardized asymptotic 95% confidence interval (CI) on the group difference [Infanrix hexa(current formulation) minus Infanrix hexa(new formulation)] for the percentage of seroprotected subjects below 10%.

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

End point title	Anti-PT, Anti-FHA, Anti-PRN antibody concentrations

End point description:

End point type	Primary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	128	129	66	
Units: EL. U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, POST (N=126,128,66)	71.8 (64.1 to 80.5)	74.7 (67.1 to 83)	75.3 (65.6 to 86.5)	
Anti-FHA, POST (N=127,129,66)	179.7 (158.4 to 203.8)	215.3 (192.5 to 240.8)	181.1 (155.8 to 210.6)	
Anti-PRN, POST (N=128,129,65)	143 (122.2 to 167.3)	142.5 (122.7 to 165.6)	161.4 (130.6 to 199.6)	

Statistical analyses

Statistical analysis title	GMC Ratios for anti-PT

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Method	ANCOVA
Parameter estimate	GMC ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.24

Notes:

[7] - The upper limit of the 95% CI on the geometric mean concentrations ratio [DTPa-HBVIPV/ Hib (current formulation) divided by Infanrix hexa(new formulation)] below1.5.

Statistical analysis title	GMC Ratios for anti-FHA

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Method	ANCOVA
Parameter estimate	GMC ratio
Point estimate	1.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.44

Notes:

[8] - The upper limit of the 95% CI on the geometric mean concentrations ratio [DTPa-HBVIPV/ Hib (current formulation) divided by Infanrix hexa(new formulation)] below1.5.

Statistical analysis title	GMC Ratios for anti-PRN

Statistical analysis description:

To demonstrate that the immunogenicity of the Infanrix hexa vaccine (preservative-free formulation) in terms of response to all vaccine antigens is non-inferior to that of the preservative-containing Infanrix hexa vaccine one month after a three-dose primary vaccination course.

Comparison groups	Infanrix Hexa NEW Group v Infanrix Hexa REF Group
Number of subjects included in analysis	257
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Method	ANCOVA
Parameter estimate	GMC ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.31

Notes:

[9] -
The upper limit of the 95% CI on the geometric mean concentrations ratio [DTPa-HBVIPV/ Hib (current formulation) divided by Infanrix hexa(new formulation)] below1.5.

Secondary: Number of subjects with vaccine response against PT (anti-PT), FHA (anti-FHA), PRN (anti-PRN) antigens

End point title	Number of subjects with vaccine response against PT (anti-PT), FHA (anti-FHA), PRN (anti-PRN) antigens

End point description:

Vaccine response was defined as the appearance of antibodies in subjects who were initially seronegative (i.e. with concentrations < cut-off value) or at least maintenance of pre-vaccination

antibody concentrations in subjects who were initially seropositive (i.e. with concentrations ³ cut-off value), taking into consideration the decreasing maternal antibodies.

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	126	129	65	
Units: Subjects				
Anti-PT, POST (N=124,128,65)	123	125	65	
Anti-FHA, POST (N=125,129,65)	123	128	65	
Anti-PRN, POST (N=126,127,64)	121	124	64	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with polyribosyl ribitol phosphate (anti-PRP) antibody concentrations ≥ 1 µg/mL

End point title	Number of subjects with polyribosyl ribitol phosphate (anti-PRP) antibody concentrations ≥ 1 µg/mL

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	106	54	
Units: Subjects				
Anti-PRP, POST (N=104,106,54)	71	82	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA) and anti-Pertactin (anti-PRN) antibody concentrations ≥ 5 EL.U/mL

End point title	Number of subjects with anti Pertussis toxoid (anti-PT), anti-Filamentous haemagglutinin (anti-FHA) and anti-Pertactin (anti-PRN) antibody concentrations ≥ 5 EL.U/mL

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	128	129	66	
Units: Subjects				
Anti-PT, POST (N=126,128,66)	125	128	66	
Anti-FHA, POST (N=127,129,66)	126	129	66	
Anti-PRN, POST (N=128,129,65)	127	129	65	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	116	123	63	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, POST (N=116,123,63)	327.6 (268.6 to 399.5)	313.5 (262.4 to 374.6)	358.6 (259.8 to 495.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

End point title	Anti-PRP antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	106	54	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, POST (N=104,106,54)	2.153 (1.59 to 2.915)	3.034 (2.284 to 4.03)	0.1 (0.085 to 0.117)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D, Anti-T antibody concentrations

End point title	Anti-D, Anti-T antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	106	54	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, POST (N=104,106,54)	0.881 (0.732 to 1.06)	0.951 (0.777 to 1.164)	0.875 (0.64 to 1.197)	
Anti-T, POST (N=104,106,54)	2.106 (1.807 to 2.454)	2.229 (1.958 to 2.539)	2.225 (1.869 to 2.648)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Polio1, Anti-Polio2,Anti-Polio3 antibody concentrations

End point title	Anti-Polio1, Anti-Polio2,Anti-Polio3 antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

At one month after (POST) Dose 3

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	71	74	37	
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio1, POST (N=60,66,31)	500.3 (383.8 to 652.3)	574.9 (423.9 to 779.7)	566.2 (384.4 to 834)	
Anti-Polio2, POST (N=64,74,36)	399.2 (297.3 to 536)	390.4 (284.9 to 534.9)	391.1 (269.6 to 567.3)	
Anti-Polio3, POST (N=71,72,37)	749.3 (592.9 to 946.9)	686.5 (525.4 to 897.1)	737.7 (552.3 to 985.4)	

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:

End point type	Secondary

End point timeframe:

During day 4 (Days 0-3) after each vaccination

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	167	83	
Units: Subjects				
Any Pain, D1 (N=167,167,83)	15	18	5	
Any Redness, D1 (N=167,167,83)	40	43	16	
Any Swelling, D1 (N=167,167,83)	18	19	6	
Any Pain, D2 (N=166,167,83)	15	19	6	
Any Redness, D2 (N=166,167,83)	50	43	22	
Any Swelling, D2 (N=166,167,83)	21	20	10	
Any Pain, D3 (N=164,167,82)	10	5	3	
Any Redness, D3 (N=164,167,82)	44	48	24	
Any Swelling, D3 (N=164,167,82)	20	23	10	
Any Pain, Across (N=167,167,83)	30	29	13	
Any Redness, Across (N=167167,83)	79	77	36	
Any Swelling, Across (N=167,167,83)	43	44	19	

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:

End point type	Secondary

End point timeframe:

During day 4 (Days 0-3) after each vaccination

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	167	83	
Units: Subjects				
Any Drowsiness, D1 (N=167,167,83)	50	49	12	
Any Fever (Axillary), D1 (N=167,167,83)	28	41	4	
Any Irritability, D1 (N=167,167,83)	41	50	15	
Any Loss of appetite, D1 (N=167,167,83)	19	22	4	
Any Drowsiness, D2 (N=166,167,83)	47	34	13	
Any Fever (Axilary), D2 (N=166,167,83)	35	30	13	
Any Irritability, D2 (N=166,167,83)	42	38	17	
Any Loss of appetite, D2 (N=166,167,83)	20	19	8	
Any Drowsiness, D3 (N=164,167,82)	22	22	9	
Any Fever (Axilary), D3 (N=164,167,82)	18	17	4	

Any Irritability, D3 (N=164,167,82)	25	30	11	
Any Loss of appetite, D3 (N=164,167,82)	11	12	4	
Any Drowsiness, Across (N=167,167,83)	67	64	21	
Any Fever (Axilary), Across (N=167167,83)	62	61	18	
Any Irritability, Across (N=167,167,83)	68	74	27	
Any Loss of appetite, Across (N=167,167,83)	39	41	12	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events

End point title	Number of subjects with unsolicited adverse events
End point description:	
End point type	Secondary
End point timeframe:	
During the 31 day (Days 0-30) after each vaccination	

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	167	83	
Units: Subjects				
Any AEs (N=167,167,83)	40	33	12	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events

End point title	Number of subjects with serious adverse events
End point description:	
End point type	Secondary
End point timeframe:	
During the entire study period	

End point values	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	167	167	83	
Units: Subjects				
Any SAEs (N=167,167,83)	1	3	1	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day post-vaccination period, Unsolicited AEs during the 31-day post-vaccination period, SAEs during the entire period.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	Infanrix Hexa NEW Group
Reporting group description: -	
Reporting group title	Infanrix Hexa REF Group
Reporting group description: -	
Reporting group title	Infanrix Penta Group

Reporting group description: -

Serious adverse events	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 167 (0.60%)	3 / 167 (1.80%)	1 / 83 (1.20%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	0 / 167 (0.00%)	1 / 167 (0.60%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory disorder			
subjects affected / exposed	1 / 167 (0.60%)	0 / 167 (0.00%)	0 / 83 (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
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 167 (0.00%)	1 / 167 (0.60%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Bronchitis			
subjects affected / exposed	0 / 167 (0.00%)	1 / 167 (0.60%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 167 (0.00%)	0 / 167 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Infanrix Hexa NEW Group	Infanrix Hexa REF Group	Infanrix Penta Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 167 (47.31%)	77 / 167 (46.11%)	36 / 83 (43.37%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed	30 / 167 (17.96%)	29 / 167 (17.37%)	13 / 83 (15.66%)
occurrences (all)	30	29	13
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	79 / 167 (47.31%)	77 / 167 (46.11%)	36 / 83 (43.37%)
occurrences (all)	79	77	36
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	43 / 167 (25.75%)	44 / 167 (26.35%)	19 / 83 (22.89%)
occurrences (all)	43	44	19
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	67 / 167 (40.12%)	64 / 167 (38.32%)	21 / 83 (25.30%)
occurrences (all)	67	64	21
Fever(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed	62 / 167 (37.13%)	61 / 167 (36.53%)	18 / 83 (21.69%)
occurrences (all)	62	61	18

Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	68 / 167 (40.72%)	74 / 167 (44.31%)	27 / 83 (32.53%)
occurrences (all)	68	74	27
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	39 / 167 (23.35%)	41 / 167 (24.55%)	12 / 83 (14.46%)
occurrences (all)	39	41	12
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	13 / 167 (7.78%)	11 / 167 (6.59%)	8 / 83 (9.64%)
occurrences (all)	13	11	8
Rhinitis			
subjects affected / exposed	13 / 167 (7.78%)	5 / 167 (2.99%)	3 / 83 (3.61%)
occurrences (all)	13	5	3

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