Clinical trial results:
A phase III, open, randomized, controlled study to demonstrate the immunogenicity, reactogenicity and safety of GSK Biologicals meningococcal serogroup ACWY conjugate vaccine (GSK134612, MenACWY-TT) co-administered with Infanrix hexa compared to individual administration of each vaccine, in healthy 12- through 23-month-old children

Summary

EudraCT number	2006-006680-23
Trial protocol	GR DE AT
Global end of trial date	27 October 2008

Results information

Result version number	v2 (current)
This version publication date	24 February 2023
First version publication date	06 March 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	109835

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00508261
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 April 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 May 2008
Global end of trial reached?	Yes
Global end of trial date	27 October 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In subjects of the MenACWY-TT + Infanrix hexa and MenACWY-TT groups:
To demonstrate the non-inferiority of the MenACWY-TT conjugate vaccine co-administered with combined DTPa-HBV-IPV/Hib vaccine to the MenACWY-TT conjugate vaccine given alone in terms of serum bactericidal antibodies (rSBA) for N. meningitidis serogroups A, C, W-135, and Y.
In subjects of the MenACWY-TT + Infanrix hexa and Infanrix hexa groups:
To demonstrate the non-inferiority of the combined DTPa-HBV-IPV/Hib vaccine co-administered with MenACWY-TT conjugate vaccine to DTPa-HBV-IPV/Hib vaccine given alone in terms of geometric mean concentrations (GMCs) of antibodies to pertussis toxoid (PT), filamentous haemagglutinin (FHA), pertactin (PRN), percentages of subjects with antibody concentrations to PRP greater than or equal to (≥) 1.0µg/ml and to HBsAg ≥ 10mIU/ml.

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination/product administration with appropriate medical treatment readily available. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for 30 days after the last vaccination/product administration.

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	01 August 2007
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	Austria: 120
Country: Number of subjects enrolled	Germany: 598
Country: Number of subjects enrolled	Greece: 75
Worldwide total number of subjects	793
EEA total number of subjects	793

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)	793
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	Overal 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	Nimenrix + Infanrix-hexa Group

Arm description:

Subjects received concomitant administration of 1 dose of Nimenrix and Infanrix-hexa vaccines at Day 0.

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

Dosage and administration details:

Single dose intramuscular injection into the left thigh at Day 0.

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

Dosage and administration details:

Single dose intramuscular injection into the right thigh at Day 0.

Arm title	Nimenrix Group

Arm description:

Subjects received a single dose of Nimenrix vaccine at Day 0, followed one month later by 1 dose of Infanrix-hexa vaccine.

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

Dosage and administration details:

Single dose intramuscular injection into the left thigh at Day 0.

Investigational medicinal product name	Infanrix-hexa
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection into the right thigh at Month 1.

Arm title	Infanrix-Hexa Group

Arm description:

Subjects received a single dose of Infanrix-Hexa vaccine at Day 0, followed one month later by 1 dose of Nimenrix 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:

Single dose intramuscular injection into the right thigh at Day 0.

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

Dosage and administration details:

Single dose intramuscular injection into the left thigh at Month 1.

Arm title	Meningitec Group

Arm description:

Subjects received 1 dose of Meningitec vaccine at Day 0 and were permitted to receive the routinely recommended Infanrix-hexa booster once the active safety follow-up of this study was completed.

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

Dosage and administration details:

Single dose intramuscular injection into the left thigh at Day 0.

Number of subjects in period 1	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group
Started	222	220	224
Completed	219	212	218
Not completed	3	8	6
Consent withdrawn by subject	3	4	4
Other, not specified	-	1	1
Migrated/moved from study area	-	1	-
Lost to follow-up	-	1	1
Serious Adverse Event	-	1	-

Number of subjects in period 1	Meningitec Group
Started	127
Completed	126
Not completed	1
Consent withdrawn by subject	-
Other, not specified	-
Migrated/moved from study area	-
Lost to follow-up	1
Serious Adverse Event	-

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix + Infanrix-hexa Group
Reporting group description:	
Subjects received concomitant administration of 1 dose of Nimenrix and Infanrix-hexa vaccines at Day 0.	
Reporting group title	Nimenrix Group
Reporting group description:	
Subjects received a single dose of Nimenrix vaccine at Day 0, followed one month later by 1 dose of Infanrix-hexa vaccine.	
Reporting group title	Infanrix-Hexa Group
Reporting group description:	
Subjects received a single dose of Infanrix-Hexa vaccine at Day 0, followed one month later by 1 dose of Nimenrix vaccine.	
Reporting group title	Meningitec Group
Reporting group description:	
Subjects received 1 dose of Meningitec vaccine at Day 0 and were permitted to receive the routinely recommended Infanrix-hexa booster once the active safety follow-up of this study was completed.	

Reporting group values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group
Number of subjects	222	220	224
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	222	220	224
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: months			
arithmetic mean	14.6	15	14.9
standard deviation	± 3.01	± 3.33	± 3.17
Gender categorical Units: Subjects			
Female	109	106	119
Male	113	114	105

Reporting group values	Meningitec Group	Total	
Number of subjects	127	793	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	

Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	127	793	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: months			
arithmetic mean	14.6		
standard deviation	± 2.99	-	
Gender categorical			
Units: Subjects			
Female	61	395	
Male	66	398	

End points

End points reporting groups

Reporting group title	Nimenrix + Infanrix-hexa Group
Reporting group description:	
Subjects received concomitant administration of 1 dose of Nimenrix and Infanrix-hexa vaccines at Day 0.	
Reporting group title	Nimenrix Group
Reporting group description:	
Subjects received a single dose of Nimenrix vaccine at Day 0, followed one month later by 1 dose of Infanrix-hexa vaccine.	
Reporting group title	Infanrix-Hexa Group
Reporting group description:	
Subjects received a single dose of Infanrix-Hexa vaccine at Day 0, followed one month later by 1 dose of Nimenrix vaccine.	
Reporting group title	Meningitec Group
Reporting group description:	
Subjects received 1 dose of Meningitec vaccine at Day 0 and were permitted to receive the routinely recommended Infanrix-hexa booster once the active safety follow-up of this study was completed.	

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers ≥ the cut-off value

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers ≥ the cut-off value[1]
End point description:	
The cut-off for the assay was greater than or equal to (≥) 1:8. The analysis was based only on subjects receiving Nimenrix vaccination at Day 0.	
End point type	Primary
End point timeframe:	
At 1 month after vaccination with Nimenrix vaccine (Month 1)	
Notes:	
[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group and the Nimenrix Group.	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	186		
Units: Subjects				
rSBA-MenA, M1 (N=193; 183)	193	180		
rSBA-MenC, M1 (N=191; 183)	191	178		
rSBA-MenW-135, M1 (N=193; 186)	193	183		
rSBA-MenY, M1 (N=192, 185)	192	180		

Statistical analyses

Statistical analysis title	Difference in subjects with rSBA-MenA titres ≥ 1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix vaccine co-administered with combined Infanrix-hexa vaccine to the Nimenrix vaccine given alone in terms of bactericidal antibodies to Neisseria meningitidis serogroup A at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Nimenrix Group
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in percentages
Point estimate	1.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	4.71

Notes:

[2] - Criterion for non-inferiority:
The lower limit of the two-sided standardized asymptotic 95% confidence interval (CI) for the group difference in the percentages of subjects with serum bactericidal antibodies using baby rabbit complement (rSBA) titer ≥1:8 is greater than or equal to the pre-defined clinical limit of -10%.

Statistical analysis title	Difference in subjects with rSAB-MenC titres ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix vaccine co-administered with combined Infanrix hexa vaccine to the Nimenrix vaccine given alone in terms of bactericidal antibodies to Neisseria meningitidis serogroup C at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Nimenrix Group
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in percentages
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	6.24

Notes:

[3] - Criterion for non-inferiority:
The lower limit of the two-sided standardized asymptotic 95% confidence interval (CI) for the group difference in the percentages of subjects with serum bactericidal antibodies using baby rabbit complement (rSBA) titer ≥1:8 is greater than or equal to the pre-defined clinical limit of -10%.

Statistical analysis title	Difference in subjects with rSAB-MenW titres ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix vaccine co-administered with combined Infanrix hexa vaccine to the Nimenrix vaccine given alone in terms of bactericidal antibodies to Neisseria meningitidis serogroup W-135 at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Nimenrix Group

Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in percentages
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.36
upper limit	4.64

Notes:

[4] - Criterion for non-inferiority:
The lower limit of the two-sided standardized asymptotic 95% confidence interval (CI) for the group difference in the percentages of subjects with serum bactericidal antibodies using baby rabbit complement (rSBA) titer ≥1:8 is greater than or equal to the pre-defined clinical limit of -10%.

Statistical analysis title	Difference in subjects with rSAB-MenY titres ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix vaccine co-administered with combined Infanrix hexa vaccine to the Nimenrix vaccine given alone in terms of bactericidal antibodies to Neisseria meningitidis serogroup Y at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Nimenrix Group
Number of subjects included in analysis	379
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in percentages
Point estimate	2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	6.18

Notes:

[5] - Criterion for non-inferiority:
The lower limit of the two-sided standardized asymptotic 95% confidence interval (CI) for the group difference in the percentages of subjects with serum bactericidal antibodies using baby rabbit complement (rSBA) titer ≥1:8 is greater than or equal to the pre-defined clinical limit of -10%.

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

End point title	Anti-PT, anti-FHA and anti-PRN concentrations[6]

End point description:

The analysis was based only on subjects receiving Infanrix-hexa vaccination. The results were calculated as geometric mean expressed in enzyme-linked immunosorbent assay (ELISA) units per milliliter (EL.U/mL).

End point type	Primary

End point timeframe:

At 1 month after the first vaccination (Month 1)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group and the Infanrix-Hexa Group.

End point values	Nimenrix + Infanrix-hexa Group	Infanrix-Hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	191	179		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, M1 (N=191; 178)	86 (77 to 95)	85 (75 to 96)		
Anti-FHA, M1 (N=191; 178)	542 (492 to 597)	544 (485 to 611)		
Anti-PRN, M1 (N=190; 179)	470 (411 to 537)	450 (387 to 522)		

Statistical analyses

Statistical analysis title	GMC ratio for anti-PT concentrations

Statistical analysis description:

To demonstrate the non-inferiority of the combined Infanrix hexa vaccine co-administered with Nimenrix vaccine to Infanrix hexa vaccine given alone in terms of geometric mean concentrations (GMCs) of antibodies to pertussis toxoid (PT) at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Infanrix-Hexa Group
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Adjusted GMC ratios
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.12

Notes:

[7] - Criterion for non-inferiority (1 month after the first study vaccination):
The lower limit of the two-sided 95% CI on the GMC ratio for anti-PT (ELISA) is greater than or equal to a pre-defined clinical limit of delta = 0.67.

Statistical analysis title	GMC ratio for anti-FHA concentrations

Statistical analysis description:

To demonstrate the non-inferiority of the combined Infanrix hexa vaccine co-administered with Nimenrix vaccine to Infanrix hexa vaccine given alone in terms of geometric mean concentrations (GMCs) of antibodies to filamentous haemagglutinin (FHA) at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Infanrix-Hexa Group
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Adjusted GMC ratios
Point estimate	0.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.13

Notes:

[8] - Criterion for non-inferiority (1 month after the first study vaccination):
The lower limit of the two-sided 95% CI on the GMC ratio for anti-FHA (ELISA) is greater than or equal to a pre-defined clinical limit of delta = 0.67.

Statistical analysis title	GMC ratio for anti-PRN concentrations

Statistical analysis description:

To demonstrate the non-inferiority of the combined Infanrix hexa vaccine co-administered with Nimenrix vaccine to Infanrix hexa vaccine given alone in terms of geometric mean concentrations (GMCs) of antibodies to pertactin (PRN) at month 1.

Comparison groups	Nimenrix + Infanrix-hexa Group v Infanrix-Hexa Group
Number of subjects included in analysis	370
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Adjusted GMC ratios
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.1

Notes:

[9] - Criterion for non-inferiority (1 month after the first study vaccination):
The lower limit of the two-sided 95% CI on the GMC ratio for anti-PRN (ELISA) is greater than or equal to a pre-defined clinical limit of delta = 0.67.

Primary: Number of subjects with anti-HBs concentrations ≥ the cut-off value

End point title	Number of subjects with anti-HBs concentrations ≥ the cut-off value[10]

End point description:

The cut-off for the assay was greater than or equal to (≥) 10 milli-interantional units per milliliter (mIU/mL).

End point type	Primary

End point timeframe:

At 1 month after vaccination with Nimenrix vaccine (Month 1)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group and the Infanrix-Hexa Group.

End point values	Nimenrix + Infanrix-hexa Group	Infanrix-Hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	181	169		
Units: Subjects				
Anti-PT, M1 (N=181; 169)	180	166		

Statistical analyses

Statistical analysis title	Difference in subjects with anti-HBs ≥10mIU/mL
Comparison groups	Nimenrix + Infanrix-hexa Group v Infanrix-Hexa Group
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	non-inferiority[11]
Parameter estimate	Difference in percentages
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.47
upper limit	4.6

Notes:

[11] - Criterion for non-inferiority (1 month after the first study vaccination):
The lower limit of the two-sided standardized asymptotic 95% CI for the group difference in the percentages of subjects with anti-HBs antibody concentrations ≥10 mIU/ml is greater than or equal to the pre-defined clinical limit of -10%.

Primary: Number of subjects with anti-PRP concentrations ≥ the cut-off value

End point title	Number of subjects with anti-PRP concentrations ≥ the cut-off value[12]

End point description:

The cut-off for the assay was ≥ 1µg/mL.

End point type	Primary

End point timeframe:

At 1 month after vaccination with Nimenrix vaccine (Month 1)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group and the Infanrix-Hexa Group.

End point values	Nimenrix + Infanrix-hexa Group	Infanrix-Hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	184	173		
Units: Subjects				
Anti-PRP, M1 (N=184; 173)	183	170		

Statistical analyses

Statistical analysis title	Difference in subjects with anti-PRP ≥1.0 µg/mL
Comparison groups	Nimenrix + Infanrix-hexa Group v Infanrix-Hexa Group
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	non-inferiority[13]
Parameter estimate	Difference in percentages
Point estimate	1.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.45
upper limit	4.5

Notes:

[13] - Criterion for non-inferiority (1 month after the first study vaccination):
The lower limit of the two-sided standardized asymptotic 95% CI for the group difference in the percentage of subjects with anti-PRP concentrations (ELISA) ≥1.0 µg/mL is greater than or equal to the pre-defined clinical limit of -10%.

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers ≥ the cut-off values

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers ≥ the cut-off values

End point description:

The cut-off values for the assay were ≥ 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193	186	179	114
Units: Subjects				
rSBA-MenA [M 0], ≥1:8 (N=84,77,72,46)	30	32	34	18
rSBA-MenA [M 1], ≥1:8 (N=193,183,163,100)	193	180	71	43
rSBA-MenA [M 2], ≥1:8 (N=0,90,178,0)	0	90	178	0
rSBA-MenA [M 0], ≥1:128 (N=84,77,72,46)	18	21	24	11
rSBA-MenA [M 1], ≥1:128 (N=193,183,163,100)	193	179	57	30
rSBA-MenA [M 2], ≥1:128 (N=0,90,178,0)	0	90	178	0
rSBA-MenC [M 0], ≥1:8 (N=93,91,92,54)	20	25	13	11
rSBA-MenC [M 1], ≥1:8 (N=191,183,177,114)	191	178	34	112
rSBA-MenC [M 2], ≥1:8 (N=0,94,178,0)	0	91	178	0
rSBA-MenC [M 0], ≥1:128 (N=93,91,92,54)	5	8	5	3
rSBA-MenC [M 1], ≥1:128 (N=191,183,177,114)	189	172	14	102

rSBA-MenC [M 2], ≥1:128 (N=0,94,178,0)	0	85	157	0
rSBA-MenW-135 [M 0], ≥1:8 (N=91,84,85,55)	43	42	46	22
rSBA-MenW-135 [M 1], ≥1:8 (N=193,186,173,112)	193	183	86	41
rSBA-MenW-135 [M 2], ≥1:8 (N=0,91,179,0)	0	91	179	0
rSBA-MenW-135 [M 0], ≥1:128 (N=91,84,85,55)	17	11	23	10
rSBA-MenW-135 [M 1] ≥1:128 (N=193,186,173,112)	193	180	49	23
rSBA-MenW-135 [M 2], ≥1:128 (N=0,91,179,0)	0	90	178	0
rSBA-MenY [M 0], ≥1:8 (N=94,87,87,55)	57	53	53	30
rSBA-MenY [M 1], ≥1:8 (N=192,185,174,110)	192	180	103	71
rSBA-MenY [M 2], ≥1:8 (N=0,92,179,0)	0	91	178	0
rSBA-MenY [M 0], ≥1:128 (N=94,87,87,55)	38	37	34	20
rSBA-MenY [M 1], ≥1:128 (N=192,185,174,110)	192	178	79	38
rSBA-MenY [M 2], ≥1:128 (N=0,92,179,0)	0	91	178	0

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers
End point description:	
The results were tabulated as geometric mean expressed in titers.	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193	186	179	114
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [M 0], (N=84,77,72,46)	15 (10 to 22.4)	19 (12.2 to 29.5)	24 (15 to 38.4)	15.9 (9.2 to 27.5)
rSBA-MenA [M 1], (N=193,183,163,100)	3152.9 (2752.5 to 3611.4)	3169.9 (2577.2 to 3898.8)	24.2 (17.4 to 33.7)	21.5 (14.5 to 32.1)

rSBA-MenA [M 2], (N=0,90,178,0)	0 (0 to 0)	2881.9 (2292 to 3623.6)	1938.3 (1699.1 to 2211.2)	0 (0 to 0)
rSBA-MenC [M 0], (N=93,91,92,54)	7.4 (5.7 to 9.6)	9.1 (6.7 to 12.2)	6.1 (4.9 to 7.7)	7.6 (5.2 to 11.2)
rSBA-MenC [M 1], (N=191,183,177,114)	879.7 (763.1 to 1014)	828.7 (672.4 to 1021.4)	7.5 (6.1 to 9.3)	691.4 (520.8 to 917.9)
rSBA-MenC [M 2], (N=0,94,178,0)	0 (0 to 0)	519.6 (391.7 to 689.2)	386 (333.9 to 446.2)	0 (0 to 0)
rSBA-MenW-135 [M 0], (N=91,84,85,55)	19 (13.1 to 27.6)	19.2 (13.3 to 27.7)	24.8 (16.7 to 36.8)	15.6 (9.8 to 25)
rSBA-MenW-135 [M 1], (N=193,186,173,112)	4147 (3670.1 to 4685.8)	4022.3 (3269.2 to 4948.8)	25.2 (18.6 to 34.2)	14.2 (10.2 to 19.7)
rSBA-MenW-135 [M 2], (N=0,91,179,0)	0 (0 to 0)	3630.1 (2899.1 to 4545.4)	2466.4 (2175.4 to 2796.4)	0 (0 to 0)
rSBA-MenY [M 0], (N=94,87,87,55)	36.8 (24.7 to 54.8)	45.4 (29.1 to 71)	41.2 (26.7 to 63.4)	32 (18.3 to 55.9)
rSBA-MenY [M 1], (N=192,185,174,110)	3461.8 (2990.1 to 4007.9)	3167.7 (2521.9 to 3978.9)	45.9 (33 to 63.9)	47.2 (32.1 to 69.3)
rSBA-MenY [M 2], (N=0,92,179,0)	0 (0 to 0)	3010.4 (2325.3 to 3897.3)	2446.9 (2088.5 to 2866.8)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY ≥ the cut-off

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY ≥ the cut-off

End point description:

The cut-off for the assay were ≥ 0.3 microgram per milliliter (µg/mL) and ≥ 2.0 µg/mL, respectively.

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	47	47	29
Units: Subjects				
Anti-PSA [Month 0], ≥0.3 (N=45,45,41,27)	4	1	1	1
Anti-PSA [Month 1], ≥0.3 (N=46,46,37,25)	46	45	1	1
Anti-PSA [Month 2], ≥0.3 (N=0,44,42,0)	0	44	42	0

Anti-PSA [Month 0], ≥2.0 (N=45,45,41,27)	0	0	0	0
Anti-PSA [Month 1], ≥2.0 (N=45,45,41,27)	46	44	1	0
Anti-PSA [Month 2], ≥2.0 (N=45,45,41,27)	0	43	40	0
Anti-PSC [Month 0], ≥0.3 (N=48,43,46,29)	1	1	2	0
Anti-PSC [Month 1], ≥0.3 (N=51,41,47,28)	51	41	2	28
Anti-PSC [Month 2], ≥0.3 (N=0,41,47,0)	0	41	47	0
Anti-PSC [Month 0], ≥2.0 (N=48,43,46,29)	1	0	0	0
Anti-PSC [Month 1], ≥2.0 (N=51,41,47,28)	50	41	0	26
Anti-PSC [Month 2], ≥2.0 (N=0,41,47,0)	0	41	43	0
Anti-PSW-135 [Month 0], ≥0.3 (N=44,43,40,26)	1	1	2	0
Anti-PSW-135 [Month 1], ≥0.3 (N=44,47,41,26)	44	43	2	0
Anti-PSW-135 [Month 2], ≥0.3 (N=0,44,41,0)	0	43	41	0
Anti-PSW-135 [Month 0], ≥2.0 (N=44,43,40,26)	0	0	1	0
Anti-PSW-135 [Month 1], ≥2.0 (N=44,47,41,26)	40	39	2	0
Anti-PSW-135 [Month 2], ≥2.0 (N=0,41,41,0)	0	36	29	0
Anti-PSY [Month 0], ≥0.3 (N=45,44,42,29)	1	1	0	0
Anti-PSY [Month 1], ≥0.3 (N=45,45,37,23)	45	43	1	0
Anti-PSY [Month 2], ≥0.3 (N=0,44,41,0)	0	44	41	0
Anti-PSY [Month 0], ≥2.0 (N=45,44,42,29)	0	0	0	0
Anti-PSY [Month 1], ≥2.0 (N=45,45,37,23)	40	42	1	0
Anti-PSY [Month 2], ≥2.0 (N=0,44,41,0)	0	40	34	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations

End point title	Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations

End point description:

The results for the assay were tabulated as geometric mean expressed in microgram per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	47	47	29
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA [M 0], (N=45,45,41,27)	0.17 (0.15 to 0.19)	0.15 (0.15 to 0.16)	0.16 (0.14 to 0.18)	0.16 (0.14 to 0.18)
Anti-PSA [M 1], (N=46,46,37,25)	31.01 (23.73 to 40.52)	33.15 (21.89 to 50.18)	0.17 (0.13 to 0.22)	0.16 (0.14 to 0.18)
Anti-PSA [M 2], (N=0,44,42,0)	0 (0 to 0)	16.93 (12.39 to 23.13)	12.28 (9.38 to 16.06)	0 (0 to 0)
Anti-PSC [M 0], (N=48,43,46,29)	0.16 (0.14 to 0.2)	0.16 (0.14 to 0.17)	0.16 (0.15 to 0.17)	0.15 (0.15 to 0.15)
Anti-PSC [M 1], (N=51,41,47,28)	13.74 (10.68 to 17.67)	23.52 (18.91 to 29.25)	0.16 (0.15 to 0.17)	7.99 (5.57 to 11.46)
Anti-PSC [M 2], (N=0,41,47,0)	0 (0 to 0)	9.73 (7.82 to 12.12)	5.84 (4.66 to 7.32)	0 (0 to 0)
Anti-PSW-135 [M 0], (N=44,43,40,26)	0.16 (0.14 to 0.17)	0.15 (0.15 to 0.16)	0.17 (0.14 to 0.22)	0.15 (0.15 to 0.15)
Anti-PSW-135 [M 1], (N=44,47,41,26)	6.43 (4.92 to 8.4)	4.15 (2.82 to 6.11)	0.18 (0.14 to 0.22)	0.15 (0.15 to 0.15)
Anti-PSW-135 [M 2], (N=0,44,41,0)	0 (0 to 0)	3.99 (2.91 to 5.48)	3.4 (2.52 to 4.59)	0 (0 to 0)
Anti-PSY [M 0], (N=45,44,42,29)	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)
Anti-PSY [M 1], (N=45,45,37,23)	6.52 (4.91 to 8.65)	9.42 (6.49 to 13.66)	0.17 (0.13 to 0.21)	0.15 (0.15 to 0.15)
Anti-PSY [M 2], (N=0,44,41,0)	0 (0 to 0)	7.86 (6.04 to 10.23)	4.76 (3.73 to 6.09)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for Anti-tetanus toxoid (anti-TT)

End point title	Number of seroprotected subjects for Anti-tetanus toxoid (anti-TT)
End point description:	
The cut-off for the assay was ≥ 0.1.	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	180	176	110
Units: Subjects				
anti-TT [M 0], ≥0.1 (N=186,177,171,108)	177	161	155	99
anti-TT [M 1], ≥0.1 (N=184,180,174,110)	184	177	173	99
anti-TT [M 2], ≥0.1 (N=0,177,176,0)	0	177	176	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-tetanus toxoid (anti-TT) antibody concentrations

End point title	Anti-tetanus toxoid (anti-TT) antibody concentrations

End point description:

The results for the assay were tabulated as geometric mean expressed in internationl units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	180	176	110
Units: IU/mL				
geometric mean (confidence interval 95%)				
anti-TT [M 0], (N=186,177,171,108)	0.481 (0.417 to 0.554)	0.39 (0.332 to 0.457)	0.416 (0.354 to 0.489)	0.393 (0.325 to 0.475)
anti-TT [M 1], (N=184,180,174,110)	10.47 (9.131 to 12.007)	7.941 (6.517 to 9.677)	6.189 (5.404 to 7.089)	0.374 (0.306 to 0.457)
anti-TT [M 2], (N=0,177,176,0)	0 (0 to 0)	13.966 (12.199 to 15.987)	8.236 (7.348 to 9.231)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroprotected for anti-diphtheria (anti-D) ≥ the cut-off

End point title	Number of subjects seroprotected for anti-diphtheria (anti-D) ≥

	the cut-off
End point description:	
The cut-off for the assay was ≥ 0.1	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	178	176	110
Units: Subjects				
anti-D [M 0], ≥0.1 (N=185,174,170,106)	169	157	154	94
anti-D [M 1], ≥0.1 (N=184,178,174,110)	184	156	173	109
anti-D [M 2], ≥0.1 (N=0,177,176,0)	0	176	176	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (anti-D) antibody concentrations

End point title	Anti-diphtheria (anti-D) antibody concentrations
End point description:	
The results for the assay were tabulated as geometric mean expressed in international units per milliliter (IU/mL).	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	178	176	110
Units: IU/mL				
geometric mean (confidence interval 95%)				
anti-D [M 0], (N=185,174,170,106)	0.477 (0.407 to 0.559)	0.476 (0.397 to 0.57)	0.437 (0.367 to 0.521)	0.452 (0.355 to 0.574)
anti-D [M 1], (N=184,178,174,110)	7.636 (6.889 to 8.465)	0.404 (0.335 to 0.487)	7.292 (6.362 to 8.358)	5.201 (4.243 to 6.376)
anti-D [M 2], (N=0,177,176,0)	0 (0 to 0)	8.561 (7.553 to 9.703)	5.21 (4.623 to 5.872)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects seroprotected for anti-polio type 1, 2 & 3 ≥ the cut-off

End point title	Number of subjects seroprotected for anti-polio type 1, 2 & 3 ≥ the cut-off
End point description:	
The cut-off for the assay was ≥ 1:8.	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	164	164	100
Units: Subjects				
anti-p1 [M 0] (N=168,161,156,100)	158	143	142	90
anti-p1 [M 1] (N=167,164,164,99)	166	149	163	89
anti-p1 [M 2] (N=0,160,162,0)	0	159	161	0
anti-p2 [M 0] (N=168,161,156,98)	153	141	145	80
anti-p2 [M 1] (N=167,164,163,98)	166	147	161	80
anti-p2 [M 2] (N=0,159,162,0)	0	159	161	0
anti-p3 [M 0] (N=168,161,157,100)	155	148	143	88
anti-p3 [M 1] (N=167,163,163,100)	167	150	160	87
anti-p3 [M 2] (N=0,160,161,0)	0	159	159	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 & 3 titers

End point title	Anti-polio type 1, 2 & 3 titers
End point description:	
The results for the assay were tabulated as geometric mean expressed in titers.	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	164	164	100
Units: Titers				
geometric mean (confidence interval 95%)				
anti-p1 [M 0] (N=168,161,156,100)	84.2 (67.2 to 105.4)	72.5 (55.6 to 94.5)	83.6 (65.5 to 106.6)	71.7 (51.7 to 99.6)
anti-p1 [M 1] (N=167,164,164,99)	984.4 (830.4 to 1167)	74.2 (56.7 to 97.3)	1308.5 (1073.2 to 1595.5)	66.3 (46.6 to 94.4)
anti-p1 [M 2] (N=0,160,162,0)	0 (0 to 0)	1288.2 (1052.5 to 1576.6)	1108.4 (913.5 to 1344.8)	0 (0 to 0)
anti-p2 [M 0] (N=168,161,156,98)	76.8 (60.8 to 97)	66.3 (50.9 to 86.5)	65.6 (51.2 to 84.2)	49.3 (34.9 to 69.6)
anti-p2 [M 1] (N=167,164,163,98)	1372 (1153.5 to 1631.9)	70.3 (53.4 to 92.6)	1540.4 (1253.2 to 1893.2)	49.8 (34.5 to 71.9)
anti-p2 [M 2] (N=0,159,162,0)	0 (0 to 0)	1650.5 (1358.5 to 2005.3)	1174.5 (961.4 to 1434.8)	0 (0 to 0)
anti-p3 [M 0] (N=168,161,157,100)	104.4 (81.1 to 134.4)	99.8 (77.5 to 128.5)	113.2 (86.9 to 147.5)	102.9 (72.8 to 145.4)
anti-p3 [M 1] (N=167,163,163,100)	2295.6 (1952.1 to 2699.4)	96.6 (74.2 to 125.8)	2034.3 (1594.9 to 2594.8)	85.3 (58.7 to 124.1)
anti-p3 [M 2] (N=0,160,161,0)	0 (0 to 0)	2478 (2049.2 to 2996.4)	1655.1 (1308.9 to 2092.9)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Numbers of seroprotected subjects for anti-PRP ≥ the cut-off

End point title	Numbers of seroprotected subjects for anti-PRP ≥ the cut-off
End point description:	
The cut-off for the assay was ≥ 1.0.	
End point type	Secondary
End point timeframe:	
At month 0, 1 and 2	

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	179	176	110
Units: Subjects				
anti-PRP [M 0] ≥1.0 (N=185,175,171,108)	73	64	65	36
anti-PRP [M 1] ≥1.0 (N=184,179,173,110)	183	70	170	34
anti-PRP [M 2] ≥1.0 (N=0,177,176,0)	0	172	170	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

End point title	Anti-PRP antibody concentrations

End point description:

The results for the assay were tabulated as geometric mean expressed in microgram per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	179	176	110
Units: µg/mL				
geometric mean (confidence interval 95%)				
anti-PRP [M 0] (N=185,175,171,108)	0.806 (0.658 to 0.987)	0.665 (0.528 to 0.839)	0.766 (0.596 to 0.986)	0.585 (0.449 to 0.762)
anti-PRP [M 1] (N=184,179,173,110)	25.556 (21.358 to 30.579)	0.711 (0.56 to 0.904)	31.165 (25.142 to 38.631)	0.55 (0.42 to 0.72)
anti-PRP [M 2] (N=0,177,176,0)	0 (0 to 0)	12.239 (10.392 to 14.414)	21.023 (17.036 to 25.942)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for anti-HBs ≥ the cut-off values

End point title	Number of seroprotected subjects for anti-HBs ≥ the cut-off

	values

End point description:

The cut-offs for the assay were ≥ 10 mIU/mL and ≥ 100 mIU/mL respectively.

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	181	174	169	106
Units: Subjects				
anti-HBS [M 0] ≥10 (N=180,169,166,102)	173	158	155	95
anti-HBS [M 1] ≥10 (N=181,174,169,106)	180	160	166	100
anti-HBS [M 2] ≥10 (N=0,173,168,0)	0	172	167	0
anti-HBS [M 0] ≥100 (N=180,169,166,102)	92	80	75	46
anti-HBS [M 1] ≥100 (N=181,174,169,106)	169	85	155	46
anti-HBS [M 2] ≥100 (N=0,173,168,0)	0	168	158	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations

End point description:

The results for the assay were tabulated as geometric mean expressed in milli-international units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	181	174	169	106
Units: mIU/mL				
geometric mean (confidence interval 95%)				
anti-HBS [M 0] (N=180,169,166,102)	111.6 (90.9 to 136.9)	92.8 (75.3 to 114.4)	101.2 (81.5 to 125.7)	85.6 (65.7 to 111.5)

anti-HBS [M 1] (N=181,174,169,106)	2048.4 (1589.3 to 2640)	95 (74.8 to 120.6)	1711.6 (1292.7 to 2266.3)	101.6 (75.5 to 136.7)
anti-HBS [M 2] (N=0,173,168,0)	0 (0 to 0)	2392.3 (1841.7 to 3107.4)	1241 (976.2 to 1577.7)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a vaccine response to PT, FHA and PRN antigens

End point title	Number of subjects with a vaccine response to PT, FHA and PRN antigens[14]

End point description:

Vaccine response to these antigens is defined as appearance of antibodies in subjects who were seronegative (antibody concentration < 5 EL.U/mL) at pre-vaccination or as at least a 2-fold increase in post-over pre-vaccination antibody concentrations in subjects seropositive at pre-vaccination. The analysis was based only on subjects receiving experimental vaccination.

End point type	Secondary

End point timeframe:

At 1 month after vaccination

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group, the Nimenrix Group and the Infanrix-Hexa Group.

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	190	178	174	
Units: Subjects				
Anti-PT (N=190,176,173)	180	169	163	
Anti-FHA (N=190,173,172)	184	159	158	
Anti-PRN (N=190,178,174)	186	173	172	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The results were tabulated as geometric mean expressed in enzyme-linked immunosorbent assay (ELISA) units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

At month 0, 1 and 2

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	194	188	182	114
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT [M 0] (N=193,187,182,112)	11 (10 to 12)	10 (8 to 11)	10 (9 to 12)	11 (9 to 13)
Anti-PT [M 1] (N=191,180,178,109)	86 (77 to 95)	8 (7 to 9)	85 (75 to 96)	9 (7 to 10)
Anti-PT [M 2] (N=0,177,179,0)	0 (0 to 0)	91 (80 to 102)	63 (55 to 71)	0 (0 to 0)
Anti-FHA [M 0] (N=193,183,181,111)	51 (44 to 59)	55 (46 to 66)	49 (41 to 57)	55 (44 to 68)
Anti-FHA [M 1] (N=191,183,178,110)	542 (492 to 597)	48 (40 to 58)	544 (485 to 611)	55 (42 to 71)
Anti-FHA [M 2] (N=0,178,176,0)	0 (0 to 0)	664 (664 to 750)	413 (366 to 465)	0 (0 to 0)
Anti-PRN [M 0] (N=194,188,182,114)	26 (23 to 31)	26 (22 to 31)	21 (17 to 24)	23 (18 to 28)
Anti-PRN [M 1] (N=190,184,179,112)	470 (411 to 537)	23 (19 to 27)	450 (387 to 522)	21 (16 to 26)
Anti-PRN [M 2] (N=0,178,178,0)	0 (0 to 0)	583 (502 to 676)	336 (286 to 395)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any and Grade 3 solicited local symptoms post-meningococcal vaccination

End point title	Number of subjects reporting any and Grade 3 solicited local symptoms post-meningococcal vaccination

End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any was defined as occurrence of any local symptom irrespective of intensity grade. Grade 3 Pain was defined as crying when limb was moved/ spontaneously painful.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) follow-up period after Nimenrix or Meningitec vaccination

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	220	217	219	126
Units: Subjects				
Any Pain	49	30	35	16
Grade 3 Pain	3	0	1	1
Any Redness	70	74	56	36
Grade 3 Redness	3	8	8	2
Any Swelling	42	36	36	23
Grade 3 Swelling	2	3	7	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any and Grade 3 solicited local symptoms post-combined diphtheria vaccination

End point title	Number of subjects reporting any and Grade 3 solicited local symptoms post-combined diphtheria vaccination[15]

End point description:

The analysis was based only on subjects receiving combined-diphtheria vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) follow-up period after Infanrix-hexa vaccination

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix + Infanrix-hexa Group, the Nimenrix Group and the Infanrix-Hexa Group.

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	220	209	221	
Units: Subjects				
Any Pain	60	65	64	
Grade 3 Pain	6	5	10	
Any Redness	70	77	99	
Grade 3 Redness	11	14	27	
Any Swelling	48	53	74	
Grade 3 Swelling	12	14	22	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited general symptoms following each dose

End point title	Number of subjects reporting any solicited general symptoms following each dose

End point description:

Solicited general symptoms assessed were drowsiness, fever, irritability and loss of appetite. Any was defined as occurrence of any general symptom irrespective of intensity grade and relationship. Subjects in the Nimenrix + Infanrix-hexa Group did not receive a second dose of vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination dose 1 (D1) and second dose (D2)

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	220	218	221	126
Units: Subjects				
Drowsiness, D1	85	56	80	29
Fever, D1	80	41	71	15
Irritability, D1	83	63	75	25
Loss of appetite, D1	51	46	51	15
Drowsiness, D2	0	63	56	0
Fever, D2	0	60	37	0
Irritability, D2	0	75	50	0
Loss of appetite, D2	0	54	38	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any rash

End point title	Number of subjects reporting any rash

End point description:

Any was defined as occurrence of at least one symptom experienced.

End point type	Secondary

End point timeframe:

Day 0 - Month 7

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	220	224	127
Units: Subjects				
Any rash	13	25	22	12

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any new onset of chronic illnesses (NOCIs)

End point title	Number of subjects reporting any new onset of chronic illnesses (NOCIs)

End point description:

Any was defined as occurrence of at least one symptom experienced.

End point type	Secondary

End point timeframe:

Day 0 - Month 7

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	220	224	127
Units: Subjects				
Any NOCIs	1	2	6	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any conditions prompting emergency room visits (ER)

End point title	Number of subjects reporting any conditions prompting emergency room visits (ER)

End point description:

Any was defined as occurrence of at least one symptom experienced.

End point type	Secondary

End point timeframe:

Day 0 - Month 7

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	220	224	127
Units: Subjects				
Any ER visits	5	3	14	6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited adverse events (AEs) after the first dose

End point title	Number of subjects reporting any unsolicited adverse events (AEs) after the first dose

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" was defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination.

End point type	Secondary

End point timeframe:

Occurring within Day 0-30 following vaccination

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	220	224	127
Units: Subjects				
Any AE(s)	71	81	83	42

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any unsolicited adverse events (AEs) after the second dose

End point title	Number of subjects reporting any unsolicited adverse events (AEs) after the second dose[16]

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" was

defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. The analysis was based only on subjects receiving a second dose of vaccination.

End point type	Secondary

End point timeframe:

Occurring within Day 0-30 following vaccination

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for the Nimenrix Group and the Infanrix-Hexa Group.

End point values	Nimenrix Group	Infanrix-Hexa Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	215	221		
Units: Subjects				
Any AE(s)	87	79		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/ incapacity.

End point type	Secondary

End point timeframe:

From dose 1 (Month 0) up to study end (Month 7)

End point values	Nimenrix + Infanrix-hexa Group	Nimenrix Group	Infanrix-Hexa Group	Meningitec Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	220	224	127
Units: Subjects				
Any SAE(s)	10	8	11	6

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs were reported throughout the entire study period (Day 0 - Month 7). Solicited symptoms were reported during a 4-day period (Day 0-Day 3) after any vaccine dose, while unsolicited AEs were collected within 31 days (Days 0-30) after vaccination.

Adverse event reporting additional description:

The solicited local and general symptoms were only collected for those subjects who filled-in their symptom sheets.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Nimenrix + Infanrix-hexa Group

Reporting group description:

Subjects received concomitant administration of 1 dose of Nimenrix and Infanrix-hexa vaccines at Day 0.

Reporting group title	Meningitec Group

Reporting group description:

Subjects received 1 dose of Meningitec vaccine at Day 0 and were permitted to receive the routinely recommended Infanrix-hexa booster once the active safety follow-up of this study was completed.

Reporting group title	Infanrix-Hexa Group

Reporting group description:

Subjects received a single dose of Infanrix-Hexa vaccine at Day 0, followed one month later by 1 dose of Nimenrix vaccine.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects received a single dose of Nimenrix vaccine at Day 0, followed one month later by 1 dose of Infanrix-hexa vaccine.

Serious adverse events	Nimenrix + Infanrix-hexa Group	Meningitec Group	Infanrix-Hexa Group
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 222 (4.50%)	6 / 127 (4.72%)	11 / 224 (4.91%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Concussion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Animal bite			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Skull fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 222 (0.90%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	1 / 127 (0.79%)	0 / 224 (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
General disorders and administration site conditions			
Cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Immune system disorders			
Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	1 / 127 (0.79%)	0 / 224 (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
Gastrointestinal disorders			
Aphthous stomatitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	1 / 127 (0.79%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Gastroenteritis alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	2 / 224 (0.89%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	2 / 224 (0.89%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	2 / 127 (1.57%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	1 / 127 (0.79%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	1 / 127 (0.79%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coxsackie viral infection alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Croup infectious			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Subcutaneous abscess			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	0 / 224 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 222 (0.45%)	0 / 127 (0.00%)	0 / 224 (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

Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	0 / 127 (0.00%)	1 / 224 (0.45%)
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			
Iron deficiency			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 222 (0.00%)	1 / 127 (0.79%)	0 / 224 (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

Serious adverse events	Nimenrix Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 220 (3.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Concussion			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 220 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Animal bite			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 220 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Contusion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	1 / 220 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 220 (0.45%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Cyst			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drowning			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			

Hypersensitivity				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Aphthous stomatitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Bronchospasm				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Rash				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Gastroenteritis				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Bronchitis alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Otitis media alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coxsackie viral infection alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Croup infectious alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subcutaneous abscess				
alternative assessment type: Non-systematic				
subjects affected / exposed	1 / 220 (0.45%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillitis				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 220 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Iron deficiency				
alternative assessment type: Non-systematic				

subjects affected / exposed	0 / 220 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Nimenrix + Infanrix-hexa Group	Meningitec Group	Infanrix-Hexa Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	166 / 222 (74.77%)	75 / 127 (59.06%)	185 / 224 (82.59%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	85 / 222 (38.29%)	29 / 127 (22.83%)	95 / 224 (42.41%)
occurrences (all)	85	29	136
General disorders and administration site conditions			
Pain			
subjects affected / exposed	68 / 222 (30.63%)	16 / 127 (12.60%)	69 / 224 (30.80%)
occurrences (all)	69	16	99
Swelling			
subjects affected / exposed	64 / 222 (28.83%)	23 / 127 (18.11%)	85 / 224 (37.95%)
occurrences (all)	64	23	110
Pyrexia			
subjects affected / exposed	83 / 222 (37.39%)	17 / 127 (13.39%)	89 / 224 (39.73%)
occurrences (all)	86	17	114
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	8 / 222 (3.60%)	3 / 127 (2.36%)	5 / 224 (2.23%)
occurrences (all)	8	3	5
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	91 / 222 (40.99%)	36 / 127 (28.35%)	103 / 224 (45.98%)
occurrences (all)	91	37	155
Psychiatric disorders			
Irritability			
subjects affected / exposed	83 / 222 (37.39%)	25 / 127 (19.69%)	93 / 224 (41.52%)
occurrences (all)	83	25	125
Infections and infestations			

Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 222 (5.41%)	8 / 127 (6.30%)	24 / 224 (10.71%)
occurrences (all)	12	8	27
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 222 (4.05%)	1 / 127 (0.79%)	10 / 224 (4.46%)
occurrences (all)	11	1	10
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 222 (2.70%)	4 / 127 (3.15%)	18 / 224 (8.04%)
occurrences (all)	6	4	18
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 222 (3.15%)	6 / 127 (4.72%)	12 / 224 (5.36%)
occurrences (all)	7	7	13
Nasopharyngitis			
subjects affected / exposed	3 / 222 (1.35%)	2 / 127 (1.57%)	11 / 224 (4.91%)
occurrences (all)	3	2	12
Otitis media			
subjects affected / exposed	4 / 222 (1.80%)	5 / 127 (3.94%)	7 / 224 (3.13%)
occurrences (all)	4	5	7
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	51 / 222 (22.97%)	15 / 127 (11.81%)	68 / 224 (30.36%)
occurrences (all)	51	15	89

Non-serious adverse events	Nimenrix Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	183 / 220 (83.18%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	89 / 220 (40.45%)		
occurrences (all)	119		
General disorders and administration site conditions			

Pain			
subjects affected / exposed	75 / 220 (34.09%)		
occurrences (all)	95		
Swelling			
subjects affected / exposed	66 / 220 (30.00%)		
occurrences (all)	89		
Pyrexia			
subjects affected / exposed	90 / 220 (40.91%)		
occurrences (all)	114		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 220 (5.00%)		
occurrences (all)	11		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	102 / 220 (46.36%)		
occurrences (all)	151		
Psychiatric disorders			
Irritability			
subjects affected / exposed	100 / 220 (45.45%)		
occurrences (all)	139		
Infections and infestations			
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	27 / 220 (12.27%)		
occurrences (all)	30		
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	16 / 220 (7.27%)		
occurrences (all)	17		
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	18 / 220 (8.18%)		
occurrences (all)	20		
Bronchitis			
alternative assessment type: Non-systematic			

subjects affected / exposed	16 / 220 (7.27%)		
occurrences (all)	18		
Nasopharyngitis			
subjects affected / exposed	12 / 220 (5.45%)		
occurrences (all)	15		
Otitis media			
subjects affected / exposed	11 / 220 (5.00%)		
occurrences (all)	12		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	78 / 220 (35.45%)		
occurrences (all)	100		

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