



Clinical trial results:

Immunogenicity and Safety Study of a Quadrivalent Meningococcal Conjugate Vaccine Versus Nimenrix®, and When Administered Alone or Concomitantly with 9vHPV and Tdap-IPV Vaccines in Healthy Adolescents

Summary

EudraCT number	2020-001665-37
Trial protocol	HU IT
Global end of trial date	11 May 2022

Results information

Result version number	v1 (current)
This version publication date	18 August 2023
First version publication date	18 August 2023

Trial information

Trial identification

Sponsor protocol code	MEQ00071
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1249-2973

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur
Sponsor organisation address	14, Espace Henry Vallée, Lyon, France, 69007
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.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	01 March 2023
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of the seroprotection rate (serum bactericidal assay using human complement [hSBA] titer greater than or equal to $\geq 1:8$) to meningococcal serogroups A, C, W and Y following the administration of a single dose of MenACYW conjugate vaccine (Group 1) compared to a single dose of Nimenrix® (Group 2).

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 March 2021
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	Hungary: 168
Country: Number of subjects enrolled	Italy: 90
Country: Number of subjects enrolled	Spain: 202
Country: Number of subjects enrolled	Singapore: 3
Worldwide total number of subjects	463
EEA total number of subjects	460

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)	0
Children (2-11 years)	229
Adolescents (12-17 years)	234

Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 21 active sites in Hungary, Italy, Spain and Singapore between 16 March 2021 to 11 May 2022.

Pre-assignment

Screening details:

A total of 463 subjects were enrolled and randomised in this study.

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, Carer, Assessor

Blinding implementation details:

Study was performed in partially observer-blind fashion: Groups 1 and 2: Investigators and study staff who conducted safety assessment, subjects, parents/legally acceptable representatives, Sponsor & laboratory personnel performing serology testing were kept blinded to vaccine received. Only study staff who prepared & administered the vaccine were not involved with safety evaluation know which vaccine was administered. Group 3: Everyone involved in study know which vaccine was administered.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially)

Arm description:

Subjects received 0.5 milliliter (mL) intramuscular injection of Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate vaccine (MenACYW Conjugate vaccine) on Day 01 and 0.5 mL intramuscular injection of 9-valent human papilloma virus (9vHPV) + tetanus, diphtheria, and acellular pertussis - inactivated polio vaccines (Tdap-IPV) (sequentially after MenACYW vaccine) at Day 31.

Arm type	Experimental
Investigational medicinal product name	Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine (MenACYW Conjugate vaccine)
Investigational medicinal product code	
Other name	MenQuadfi®
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 01.

Investigational medicinal product name	Human Papillomavirus 9-valent Vaccine (9vHPV)
Investigational medicinal product code	
Other name	Gardasil® 9
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 31.

Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine (Tdap-IPV)
Investigational medicinal product code	
Other name	Repevax®/Triaxis®/Adacel®Polio

Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 31.

Arm title	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
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Arm description:

Subjects received 0.5 mL intramuscular injection of Nimenrix® vaccine on Day 01 and 0.5 mL intramuscular injection of 9vHPV + Tdap-IPV vaccines (sequentially after Nimenrix® vaccine) at Day 31.

Arm type	Active comparator
Investigational medicinal product name	Meningococcal group A, C, W-135, and Y Conjugate vaccine
Investigational medicinal product code	
Other name	Nimenrix®
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL intramuscular injection on Day 01.

Investigational medicinal product name	Human Papillomavirus 9-valent Vaccine (9vHPV)
Investigational medicinal product code	
Other name	Gardasil® 9
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 31.

Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine (Tdap-IPV)
Investigational medicinal product code	
Other name	Repevax®/Triaxis®/Adacel®Polio
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 31.

Arm title	Group3:MenACYW Conjugate+9vHPV+TdapIPV Vaccines(Concomitantly)
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Arm description:

Subjects received 0.5 mL intramuscular injection of MenACYW Conjugate vaccine concomitantly with 9vHPV + Tdap-IPV vaccines on Day 01.

Arm type	Experimental
Investigational medicinal product name	Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine (MenACYW Conjugate vaccine)
Investigational medicinal product code	
Other name	MenQuadfi®
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL intramuscular injection on Day 01.

Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed Combined with Inactivated Poliomyelitis Vaccine (Tdap-IPV)
Investigational medicinal product code	
Other name	Repevax®/Triaxis®/Adacel®Polio

Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5-mL intramuscular injection on Day 01.	
Investigational medicinal product name	Human Papillomavirus 9-valent Vaccine (9vHPV)
Investigational medicinal product code	
Other name	Gardasil® 9
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5-mL intramuscular injection on Day 01.	

Number of subjects in period 1	Group1:MenACYW Conjugate+9vHPV+ Tdap-IPV Vaccines(Sequentiall	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9vHPV+ TdapIPV Vaccines(Concomita
Started	173	173	117
Safety Analysis Set	171	171	116
Vaccinated at Day 01	170	172	116
Vaccinated at Day 31	168	169	0
Completed	167	165	116
Not completed	6	8	1
Lost to follow-up	2	2	-
Withdrawal by parent/guardian	2	3	-
Withdrawal by subject	2	1	-
Protocol deviation	-	2	1

Baseline characteristics

Reporting groups

Reporting group title	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially)
Reporting group description: Subjects received 0.5 milliliter (mL) intramuscular injection of Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate vaccine (MenACYW Conjugate vaccine) on Day 01 and 0.5 mL intramuscular injection of 9-valent human papilloma virus (9vHPV) + tetanus, diphtheria, and acellular pertussis - inactivated polio vaccines (Tdap-IPV) (sequentially after MenACYW vaccine) at Day 31.	
Reporting group title	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
Reporting group description: Subjects received 0.5 mL intramuscular injection of Nimenrix® vaccine on Day 01 and 0.5 mL intramuscular injection of 9vHPV + Tdap-IPV vaccines (sequentially after Nimenrix® vaccine) at Day 31.	
Reporting group title	Group3:MenACYW Conjugate+9vHPV+TdapIPV Vaccines(Concomitantly)
Reporting group description: Subjects received 0.5 mL intramuscular injection of MenACYW Conjugate vaccine concomitantly with 9vHPV + Tdap-IPV vaccines on Day 01.	

Reporting group values	Group1:MenACYW Conjugate+9vHPV+ Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9vHPV+ TdapIPV Vaccines(Concomitantly)
Number of subjects	173	173	117
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	12.4	12.8	12.5
standard deviation	± 2.32	± 2.38	± 2.47
Gender categorical Units: Subjects			
Female	49	57	45
Male	124	116	72
Race Units: Subjects			
American Indian or Alaska Native	2	1	0
Asian	2	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	3	1	1
White	165	169	115
More than one race	1	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	463		

Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	151		
Male	312		
Race			
Units: Subjects			
American Indian or Alaska Native	3		
Asian	5		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	5		
White	449		
More than one race	1		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially)
Reporting group description: Subjects received 0.5 milliliter (mL) intramuscular injection of Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate vaccine (MenACYW Conjugate vaccine) on Day 01 and 0.5 mL intramuscular injection of 9-valent human papilloma virus (9vHPV) + tetanus, diphtheria, and acellular pertussis - inactivated polio vaccines (Tdap-IPV) (sequentially after MenACYW vaccine) at Day 31.	
Reporting group title	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
Reporting group description: Subjects received 0.5 mL intramuscular injection of Nimenrix® vaccine on Day 01 and 0.5 mL intramuscular injection of 9vHPV + Tdap-IPV vaccines (sequentially after Nimenrix® vaccine) at Day 31.	
Reporting group title	Group3:MenACYW Conjugate+9vHPV+TdapIPV Vaccines(Concomitantly)
Reporting group description: Subjects received 0.5 mL intramuscular injection of MenACYW Conjugate vaccine concomitantly with 9vHPV + Tdap-IPV vaccines on Day 01.	

Primary: Percentage of Subjects With Antibody Titers $\geq 1:8$ Against Meningococcal Serogroups A, C, W, and Y Measured by hSBA Following Vaccination With MenACYW Conjugate Vaccine or Nimenrix® (Non-inferiority Analysis): Groups 1 and 2

End point title	Percentage of Subjects With Antibody Titers $\geq 1:8$ Against Meningococcal Serogroups A, C, W, and Y Measured by hSBA Following Vaccination With MenACYW Conjugate Vaccine or Nimenrix® (Non-inferiority Analysis): Groups 1 and 2 ^[1]
End point description: Antibody titers against meningococcal serogroups A, C, W, and Y were measured by serum bactericidal assay using human complement (hSBA). Non-inferiority data analysis for this endpoint was planned to be conducted only for Groups 1 and 2, not for Group 3. Group 3 data is reported separately. Analysis was performed on hSBA Per-Protocol Analysis Set for meningococcal vaccines (PPASM) which was a subset that included all subjects who received a dose of the study vaccine and had a valid post-vaccination serology result. The subjects who presented protocol deviations were excluded from PPASM. Here, 'n'=subjects with available data for each specified category.	
End point type	Primary
End point timeframe: Day 31 (post-vaccination)	

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: Data is reported for all applicable arms in the study.

End point values	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	161		
Units: percentage of subjects				
number (confidence interval 95%)				

Serogroup A (n=159,160)	97.5 (93.7 to 99.3)	92.5 (87.3 to 96.1)		
Serogroup C (n=159,161)	100 (97.7 to 100)	95.0 (90.4 to 97.8)		
Serogroup W (n=159,161)	100 (97.7 to 100)	98.8 (95.6 to 99.8)		
Serogroup Y (n=158,160)	99.4 (96.5 to 100)	98.1 (94.6 to 99.6)		

Statistical analyses

Statistical analysis title	Serogroup A
Comparison groups	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially) v Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[2]
Parameter estimate	Difference in Percentage
Point estimate	4.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	10.36

Notes:

[2] - The two-sided 95 percent (%) confidence interval (CI) was calculated based on the Wilson score method without continuity correction. The non-inferiority was demonstrated if the lower limit of the 95% CI of the percentage difference between compared groups was greater than (>) -10%.

Statistical analysis title	Serogroup W
Comparison groups	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially) v Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[3]
Parameter estimate	Difference in Percentage
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.28
upper limit	4.42

Notes:

[3] - The two-sided 95% CI was calculated based on the Wilson score method without continuity correction. The non-inferiority was demonstrated if the lower limit of the 95% CI of the percentage difference between compared groups was greater > -10%.

Statistical analysis title	Serogroup Y
Comparison groups	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially) v Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)

Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[4]
Parameter estimate	Difference in Percentage
Point estimate	1.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	4.77

Notes:

[4] - The two-sided 95% CI was calculated based on the Wilson score method without continuity correction. The non-inferiority was demonstrated if the lower limit of the 95% CI of the percentage difference between compared groups was greater > -10%.

Statistical analysis title	Serogroup C
Comparison groups	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially) v Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
Number of subjects included in analysis	320
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
Parameter estimate	Difference in Percentage
Point estimate	4.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.58
upper limit	9.5

Notes:

[5] - The two-sided 95% CI was calculated based on the Wilson score method without continuity correction. The non-inferiority was demonstrated if the lower limit of the 95% CI of the percentage difference between compared groups was greater > -10%.

Secondary: Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W

End point title	Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W
End point description:	
GMT titers against Meningococcal Serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on hSBA PPASM. Here, 'n'=subjects with available data for each specified category.	
End point type	Secondary
End point timeframe:	
Day 01 (pre-vaccination) and Day 31 (post-vaccination)	

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	161	113	
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A: Day 01 (n=158,160,112)	6.95 (6.18 to 7.83)	6.41 (5.67 to 7.26)	7.38 (6.23 to 8.75)	
Serogroup A: Day 31 (n=159,160,113)	78.2 (64.6 to 94.7)	56.0 (44.0 to 71.2)	42.2 (32.5 to 54.7)	
Serogroup C: Day 01 (n=158,160,113)	6.40 (5.17 to 7.92)	5.51 (4.59 to 6.62)	5.67 (4.51 to 7.14)	
Serogroup C: Day 31 (n=159,161,113)	2294 (1675 to 3142)	619 (411 to 931)	1938 (1365 to 2752)	
Serogroup Y: Day 01 (n=159,161,113)	2.56 (2.27 to 2.89)	3.14 (2.63 to 3.75)	2.43 (2.09 to 2.84)	
Serogroup Y: Day 31 (n=158,160,113)	169 (141 to 202)	84.8 (68.3 to 105)	171 (138 to 211)	
Serogroup W: Day 01 (n=159,161,112)	3.76 (3.22 to 4.40)	4.36 (3.68 to 5.17)	3.98 (3.18 to 4.96)	
Serogroup W: Day 31 (n=159,161,113)	134 (109 to 164)	64.6 (52.5 to 79.4)	74.6 (61.8 to 90.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers $\geq 1:4$ and $\geq 1:8$ Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Subjects With hSBA Antibody Titers $\geq 1:4$ and $\geq 1:8$ Against Meningococcal Serogroups A, C, Y, and W
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End point description:

Antibody titers against Meningococcal Serogroups A, C, Y and W were measured by hSBA. Percentage of subjects With hSBA antibody titers $\geq 1:4$ and $\geq 1:8$ for serogroups A, C, Y, and W were reported in the endpoint. Analysis was performed on hSBA PPASM. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	161	113	
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: $\geq 1:4$: Day 01 (n=158,160,112)	94.3 (89.5 to 97.4)	88.1 (82.1 to 92.7)	83.9 (75.8 to 90.2)	
Serogroup A: $\geq 1:8$: Day 01 (n=158,160,112)	56.3 (48.2 to 64.2)	50.6 (42.6 to 58.6)	58.9 (49.2 to 68.1)	
Serogroup A: $\geq 1:4$: Day 31 (n=159,160,113)	98.7 (95.5 to 99.8)	95.0 (90.4 to 97.8)	96.5 (91.2 to 99.0)	
Serogroup A: $\geq 1:8$: Day 31 (n=159,160,113)	97.5 (93.7 to 99.3)	92.5 (87.3 to 96.1)	91.2 (84.3 to 95.7)	
Serogroup C: $\geq 1:4$: Day 01 (n=158,160,113)	61.4 (53.3 to 69.0)	61.3 (53.2 to 68.8)	57.5 (47.9 to 66.8)	
Serogroup C: $\geq 1:8$: Day 01 (n=158,160,113)	41.1 (33.4 to 49.2)	35.6 (28.2 to 43.6)	41.6 (32.4 to 51.2)	
Serogroup C: $\geq 1:4$: Day 31 (n=159,161,113)	100 (97.7 to 100)	96.3 (92.1 to 98.6)	99.1 (95.2 to 100)	
Serogroup C: $\geq 1:8$: Day 31 (n=159,161,113)	100 (97.7 to 100)	95.0 (90.4 to 97.8)	99.1 (95.2 to 100)	
Serogroup Y: $\geq 1:4$: Day 01 (n=159,161,113)	14.5 (9.4 to 20.9)	17.4 (11.9 to 24.1)	8.8 (4.3 to 15.7)	
Serogroup Y: $\geq 1:8$: Day 01 (n=159,161,113)	9.4 (5.4 to 15.1)	15.5 (10.3 to 22.1)	6.2 (2.5 to 12.3)	
Serogroup Y: $\geq 1:4$: Day 31 (n=158,160,113)	99.4 (96.5 to 100)	98.8 (95.6 to 99.8)	100 (96.8 to 100)	
Serogroup Y: $\geq 1:8$: Day 31 (n=158,160,113)	99.4 (96.5 to 100)	98.1 (94.6 to 99.6)	100 (96.8 to 100)	
Serogroup W: $\geq 1:4$: Day 01 (n=159,161,112)	39.6 (32.0 to 47.7)	46.6 (38.7 to 54.6)	30.4 (22.0 to 39.8)	
Serogroup W: $\geq 1:8$: Day 01 (n=159,161,112)	22.6 (16.4 to 29.9)	28.6 (21.7 to 36.2)	26.8 (18.9 to 36.0)	
Serogroup W: $\geq 1:4$: Day 31 (n=159,161,113)	100 (97.7 to 100)	98.8 (95.6 to 99.8)	100 (96.8 to 100)	
Serogroup W: $\geq 1:8$: Day 31 (n=159,161,113)	100 (97.7 to 100)	98.8 (95.6 to 99.8)	99.1 (95.2 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With ≥ 4 -Fold Rise In hSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Subjects With ≥ 4 -Fold Rise In hSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W
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End point description:

Antibody titers against Meningococcal Serogroups A, C, Y and W were measured by hSBA. Fold-rise was calculated as ratio of post-dose titer on Day 31 to pre-dose titer on Day 01. Analysis was performed on hSBA PPASM. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

From Baseline (Day 01) to Day 31 (post-vaccination)

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	161	113	
Units: percentage of Subjects				
number (confidence interval 95%)				
Serogroup A (n=158,159,112)	88.0 (81.9 to 92.6)	76.1 (68.7 to 82.5)	65.2 (55.6 to 73.9)	
Serogroup C (n=158,160,113)	99.4 (96.5 to 100)	91.9 (86.5 to 95.6)	97.3 (92.4 to 99.4)	
Serogroup Y (n=158,160,113)	98.7 (95.5 to 99.8)	92.5 (87.3 to 96.1)	99.1 (95.2 to 100)	
Serogroup W (n=159,161,112)	94.3 (89.5 to 97.4)	88.2 (82.2 to 92.7)	86.6 (78.9 to 92.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Subjects With Vaccine Seroresponse Against Meningococcal Serogroups A, C, Y, and W
End point description:	
Antibody titers against meningococcal serogroups A, C, Y, and W were measured by hSBA. The vaccine seroresponse was defined as a post-vaccination hSBA titer greater than or equal to (\geq) 1:16 for subjects with pre-vaccination hSBA titer less than ($<$) 1:8, or a \geq 4-fold increase in hSBA titer from pre-vaccination to post-vaccination for subjects with pre-vaccination hSBA titer \geq 1:8. Analysis was performed on hSBA PPASM. Here, 'n'=subjects with available data for each specified category.	
End point type	Secondary
End point timeframe:	
Day 31 (post-vaccination)	

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	159	161	113	
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroups A (n=158,159,112)	88.0 (81.9 to 92.6)	75.5 (68.0 to 81.9)	63.4 (53.8 to 72.3)	
Serogroups C (n=158,160,113)	99.4 (96.5 to 100)	88.8 (82.8 to 93.2)	97.3 (92.4 to 99.4)	

Serogroups Y (n=158,160,113)	98.7 (95.5 to 99.8)	88.1 (82.1 to 92.7)	99.1 (95.2 to 100)	
Serogroups W (n=159,161,112)	93.1 (88.0 to 96.5)	81.4 (74.5 to 87.1)	85.7 (77.8 to 91.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Antibodies Measured by Serum Bactericidal Assay Using Baby Rabbit Complement (rSBA) Against Meningococcal Serogroup C: Meningococcal Serogroup C Conjugate Vaccine (MenC) Primed subjects in Groups 1 and 2

End point title	Geometric Mean Titers (GMTs) of Antibodies Measured by Serum Bactericidal Assay Using Baby Rabbit Complement (rSBA) Against Meningococcal Serogroup C: Meningococcal Serogroup C Conjugate Vaccine (MenC) Primed subjects in Groups 1 and 2 ^[6]
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End point description:

GMT titers against Serogroup C in MenC primed subjects (subjects who received monovalent MenC priming in infancy < 2 years of age) were measured by rSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on subjects who were MenC primed subjects. Here, "number of subjects analysed" signifies subjects with available data for this endpoint. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	37		
Units: titers				
geometric mean (confidence interval 95%)				
Day 01	6.51 (3.56 to 11.9)	3.32 (2.24 to 4.91)		
Day 31	19760 (13308 to 29338)	7052 (4706 to 10567)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against

Meningococcal Serogroup C: Meningococcal Serogroup C Conjugate Vaccine (MenC) Primed Subjects in Groups 1 and 2

End point title	Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against Meningococcal Serogroup C: Meningococcal Serogroup C Conjugate Vaccine (MenC) Primed Subjects in Groups 1 and 2 ^[7]
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End point description:

GMT titers against Serogroup C in MenC primed subjects (subjects who received monovalent MenC priming in infancy < 2 years of age) were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on subjects who were MenC primed, received a dose of the study vaccine and had a valid post-vaccination serology result. The subjects who presented protocol deviations were excluded. Here, 'n' = subjects with available data for specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

Notes:

[7] - 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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	114	112		
Units: titers				
geometric mean (confidence interval 95%)				
Day 01 (n=113,111)	7.30 (5.64 to 9.45)	7.06 (5.57 to 8.95)		
Day 31 (n=114,112)	4222 (3166 to 5632)	2361 (1740 to 3204)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Diphtheria, Tetanus Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Concentrations (GMCs) of Anti-Diphtheria, Tetanus Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2 ^[8]
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End point description:

Geometric mean concentrations to anti-Diphtheria, and tetanus antibodies were measured by electro chemiluminescent method. Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis performed on Per-Protocol Analysis Set for concomitant vaccines (PPASC) which was a subset that included all subjects who received a dose of study vaccine and had a valid post-vaccination serology result. Subjects who presented protocol deviations and who did not produce a valid test result were excluded from PPASC. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-vaccination)

Notes:

[8] - 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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		
Units: International units/millilitre(IU/mL)				
geometric mean (confidence interval 95%)				
Anti-Tetanus: Day 31 (n=147,147)	25.5 (22.0 to 29.5)	18.4 (15.8 to 21.5)		
Anti-Tetanus: Day 61 (n=149,147)	17.3 (14.9 to 20.1)	16.1 (14.1 to 18.5)		
Anti-Diphtheria: Day 31 (n=147,147)	0.200 (0.169 to 0.238)	0.215 (0.181 to 0.254)		
Anti-Diphtheria: Day 61 (n=149,147)	3.75 (3.24 to 4.35)	3.88 (3.37 to 4.47)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Polio Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Concentrations (GMCs) of Anti-Polio Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2 ^[9]
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End point description:

GMCs of anti-poliovirus types 1, 2, and 3 were measured by neutralization assay. Concentrations were expressed in terms of titers (1/dilution). Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-vaccination)

Notes:

[9] - 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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		
Units: titers				
geometric mean (confidence interval 95%)				
Anti-Polio type 1: Day 31 (n=147,146)	94.7 (75.5 to 119)	109 (86.0 to 138)		
Anti-Polio type 1: Day 61 (n=149,147)	3135 (2692 to 3650)	3266 (2778 to 3840)		
Anti-Polio type 2: Day 31 (n=147,147)	227 (184 to 281)	234 (188 to 292)		
Anti-Polio type 2: Day 61 (n=147,147)	3344 (2635 to 4245)	2648 (2074 to 3381)		
Anti-Polio type 3: Day 31 (n=147,147)	135 (105 to 174)	155 (120 to 200)		
Anti-Polio type 3: Day 61 (n=149,147)	7059 (5861 to 8502)	5591 (4647 to 6728)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2 ^[10]
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End point description:

GMCs of anti-pertussis antibodies (pertussis toxoid [PT], filamentous hemagglutinin [FHA], pertactin [PRN]) and fimbriae types 2 and 3 [FIM] were measured by electro chemiluminescent method. Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-vaccination)

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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		

Units: Endotoxin units per millilitre (EU/mL)				
geometric mean (confidence interval 95%)				
Anti-PT: Day 31 (n=145,147)	11.9 (10.2 to 13.8)	12.3 (10.5 to 14.4)		
Anti-PT: Day 61 (n=149,147)	58.4 (50.6 to 67.4)	59.3 (51.1 to 68.8)		
Anti-FHA: Day 31 (n=147,147)	47.3 (40.9 to 54.7)	58.3 (51.4 to 66.1)		
Anti-FHA: Day 61 (n=149,147)	177 (156 to 200)	210 (187 to 236)		
Anti-PRN: Day 31 (n=147,147)	14.5 (11.2 to 18.8)	18.2 (14.0 to 23.7)		
Anti-PRN: Day 61 (n=149,147)	331 (265 to 414)	394 (316 to 491)		
Anti-FIM: Day 31 (n=147,147)	2.74 (2.23 to 3.37)	3.18 (2.56 to 3.95)		
Anti-FIM: Day 61 (n=149,147)	152 (112 to 207)	194 (140 to 271)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Polio Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3

End point title	Geometric Mean Concentrations (GMCs) of Anti-Polio Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3 ^[11]
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End point description:

GMCs of anti-poliovirus types 1, 2, and 3 were measured by neutralisation assay. Concentrations were expressed in terms of titers (1/dilution). Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

Notes:

[11] - 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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: titers				
geometric mean (confidence interval 95%)				

Anti-Polio type 1: Day 01	146 (112 to 190)			
Anti-Polio type 1: Day 31	1593 (1306 to 1943)			
Anti-Polio type 2: Day 01	225 (178 to 285)			
Anti-Polio type 2: Day 31	2950 (2409 to 3613)			
Anti-Polio type 3: Day 01	221 (162 to 302)			
Anti-Polio type 3: Day 31	3166 (2553 to 3926)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Diphtheria, Tetanus Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3

End point title	Geometric Mean Concentrations (GMCs) of Anti-Diphtheria, Tetanus Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3 ^[12]
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End point description:

Geometric mean concentrations to anti-Diphtheria, and tetanus antibodies were measured by electro chemiluminescent method. Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-Tetanus: Day 01	0.708 (0.574 to 0.874)			
Anti-Tetanus: Day 31	34.5 (30.1 to 39.6)			
Anti-Diphtheria: Day 01	0.256 (0.208 to 0.316)			
Anti-Diphtheria: Day 31	2.91 (2.46 to 3.44)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3

End point title	Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3 ^[13]
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End point description:

GMCs of anti-pertussis antibodies (PT, FHA, PRN and FIM) antibodies were measured by electro chemiluminescent method. Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

Notes:

[13] - 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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: EU/mL				
geometric mean (confidence interval 95%)				
Anti-PT: Day 01	8.77 (7.07 to 10.9)			
Anti-PT: Day 31	41.4 (36.1 to 47.4)			
Anti-FHA: Day 01	44.5 (37.5 to 52.9)			
Anti-FHA: Day 31	146 (128 to 166)			
Anti-PRN: Day 01	11.4 (8.40 to 15.6)			
Anti-PRN: Day 31	236 (184 to 303)			
Anti-FIM: Day 01	2.32 (1.84 to 2.94)			
Anti-FIM: Day 31	106 (75.3 to 149)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations Ratios (GMCRs) of Antibodies Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Concentrations Ratios (GMCRs) of Antibodies Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2 ^[14]
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End point description:

Anti-Diphtheria, Tetanus, and Pertussis (PT, FHA, FIM, and PRN) antibodies were measured by electro chemiluminescent method. Anti-poliovirus types 1, 2, and 3 were measured by neutralisation assay. GMCRs were calculated as the ratio of GMCs at Day 61 and Day 31. Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		
Units: ratio				
geometric mean (confidence interval 95%)				
Anti-Tetanus (n=147,147)	0.677 (0.646 to 0.710)	0.876 (0.824 to 0.931)		
Anti-Diphtheria (n=147,147)	18.5 (15.3 to 22.5)	18.1 (15.1 to 21.7)		
Anti-Polio type 1 (n=147,146)	32.9 (24.5 to 44.2)	29.5 (22.1 to 39.4)		
Anti-Polio type 2 (n=145,147)	14.9 (10.8 to 20.5)	11.3 (8.09 to 15.8)		
Anti-Polio type 3 (n=147,147)	51.8 (38.0 to 70.5)	36.1 (26.7 to 48.8)		
Anti-PT (n=145,147)	4.90 (4.36 to 5.51)	4.83 (4.33 to 5.38)		
Anti-FHA (n=147,147)	3.76 (3.24 to 4.35)	3.61 (3.18 to 4.09)		

Anti-PRN (n=147,147)	22.4 (17.9 to 27.9)	21.6 (16.9 to 27.7)		
Anti-FIM (n=147,147)	55.3 (44.4 to 68.9)	61.2 (49.4 to 75.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations Ratios (GMCRs) of Antibodies Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3

End point title	Geometric Mean Concentrations Ratios (GMCRs) of Antibodies Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3 ^[15]
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End point description:

Anti-Diphtheria, Tetanus, and Pertussis (PT, FHA, FIM, and PRN) antibodies were measured by electro chemiluminescent method. Anti-poliovirus types 1, 2, and 3 were measured by neutralisation assay. GMCRs were calculated as the ratio of GMCs at Day 31/Day 01. Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: ratio				
geometric mean (confidence interval 95%)				
Anti-Tetanus	48.7 (40.1 to 59.3)			
Anti-Diphtheria	11.4 (9.17 to 14.1)			
Anti-Polio type 1	10.9 (7.77 to 15.4)			
Anti-Polio type 2	13.1 (9.66 to 17.8)			
Anti-Polio type 3	14.3 (10.1 to 20.3)			
Anti-PT	4.72 (4.05 to 5.49)			
Anti-FHA	3.27 (2.82 to 3.80)			

Anti-PRN	20.6 (15.7 to 27.1)			
Anti-FIM	45.7 (35.7 to 58.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers Above Predefined Thresholds Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2

End point title	Percentage of Subjects With Antibody Titers Above Predefined Thresholds Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine in Groups 1 and 2 ^[16]
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End point description:

Antibody titers above predefined thresholds against Tdap-IPV vaccine antigens were defined as: Anti-D Ab titers and Anti-T Ab titers ≥ 0.1 IU/mL, and ≥ 1.0 IU/mL; Anti-Polio 1, 2, and 3 Ab titers ≥ 8 (1/dilution). Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-T: Day 31: ≥ 0.1 (n=147,147)	100 (97.5 to 100)	100 (97.5 to 100)		
Anti-T: Day 31: ≥ 1.0 (n=147,147)	100 (97.5 to 100)	98.0 (94.2 to 99.6)		
Anti-T: Day 61: ≥ 0.1 (n=149,147)	100 (97.6 to 100)	100 (97.5 to 100)		
Anti-T: Day 61: ≥ 1.0 (n=149,147)	99.3 (96.3 to 100)	100 (97.5 to 100)		
Anti-D: Day 31: ≥ 0.1 (n=147,147)	76.9 (69.2 to 83.4)	79.6 (72.2 to 85.8)		
Anti-D: Day 31: ≥ 1.0 (n=147,147)	4.8 (1.9 to 9.6)	4.8 (1.9 to 9.6)		
Anti-D: Day 61: ≥ 0.1 (n=149,147)	100 (97.6 to 100)	100 (97.5 to 100)		
Anti-D: Day 61: ≥ 1.0 (n=149,147)	93.3 (88.0 to 96.7)	92.5 (87.0 to 96.2)		
Anti-Polio 1: Day 31: ≥ 8 (n=147,146)	95.2 (90.4 to 98.1)	95.2 (90.4 to 98.1)		

Anti-Polio 1: Day 61: ≥ 8 (n=149,147)	100 (97.6 to 100)	100 (97.5 to 100)		
Anti-Polio 2: Day 31: ≥ 8 (n=147,147)	99.3 (96.3 to 100)	100 (97.5 to 100)		
Anti-Polio 2: Day 61: ≥ 8 (n=147,147)	100 (97.5 to 100)	100 (97.5 to 100)		
Anti-Polio 3: Day 31: ≥ 8 (n=147,147)	95.9 (91.3 to 98.5)	96.6 (92.2 to 98.9)		
Anti-Polio 3: Day 61: ≥ 8 (n=149,147)	100 (97.6 to 100)	100 (97.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers Above Predefined Thresholds Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3

End point title	Percentage of Subjects With Antibody Titers Above Predefined Thresholds Against Antigens Contained in Tetanus, Diphtheria, and Acellular Pertussis - Inactivated Polio Vaccine (Tdap-IPV) Vaccine: Group 3 ^[17]
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End point description:

Antibody titers above predefined thresholds against Tdap-IPV vaccine antigens were defined as: Anti-D Ab titers and Anti-T Ab titers ≥ 0.1 IU/mL, and ≥ 1.0 IU/mL; Anti-Polio 1, 2, and 3 Ab titers ≥ 8 (1/dilution). Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

Notes:

[17] - 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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-T: Day 01: ≥ 0.1	96.5 (91.2 to 99.0)			
Anti-T: Day 01: ≥ 1.0	38.9 (29.9 to 48.6)			
Anti-T: Day 31: ≥ 0.1	100 (96.8 to 100)			
Anti-T: Day 31: ≥ 1.0	100 (96.8 to 100)			
Anti-D: Day 01: ≥ 0.1	85.0 (77.0 to 91.0)			

Anti-D: Day 01: ≥ 1.0	9.7 (5.0 to 16.8)			
Anti-D: Day 31: ≥ 0.1	99.1 (95.2 to 100)			
Anti-D: Day 31: ≥ 1.0	90.3 (83.2 to 95.0)			
Anti-Polio 1: Day 01: ≥ 8	99.1 (95.2 to 100)			
Anti-Polio 1: Day 31: ≥ 8	100 (96.8 to 100)			
Anti-Polio 2: Day 01: ≥ 8	100 (96.8 to 100)			
Anti-Polio 2: Day 31: ≥ 8	100 (96.8 to 100)			
Anti-Polio 3: Day 01: ≥ 8	96.5 (91.2 to 99.0)			
Anti-Polio 3: Day 31: ≥ 8	100 (96.8 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Against Pertussis Antigens

End point title	Percentage of Subjects With Vaccine Seroresponse Against Pertussis Antigens
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End point description:

Vaccine seroresponse was defined as post-vaccination concentration $\geq 4 \times$ Baseline concentration, if the anti-pertussis antibody concentration at Baseline was $< 4 \times$ lower limit of quantification (LLOQ), or $\geq 2 \times$ Baseline concentration, if the anti-pertussis antibody concentration at Baseline was $\geq 4 \times$ LLOQ. Analysis was performed on PPASC. Here, 'n'=subjects with available data for each specified category. Post vaccine seroresponse for anti-pertussis antigens was Day 31 for Group 3 and Day 61 for Groups 1 and 2.

End point type	Secondary
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End point timeframe:

Day 61 (post-vaccination for Groups 1 and 2) and Day 31 (post-vaccination for Group 3)

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	149	147	113	
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-PT (n=145,147,113)	81.4 (74.1 to 87.4)	83.0 (75.9 to 88.7)	76.1 (67.2 to 83.6)	
Anti-FHA (n=147,147,113)	74.8 (67.0 to 81.6)	76.2 (68.5 to 82.8)	70.8 (61.5 to 79.0)	

Anti-PRN (n=147,147,113)	98.0 (94.2 to 99.6)	94.6 (89.6 to 97.6)	91.2 (84.3 to 95.7)	
Anti-FIM (n=147,147,113)	93.9 (88.7 to 97.2)	97.3 (93.2 to 99.3)	95.6 (90.0 to 98.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Titers (GMTs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine in Groups 1 and 2 ^[18]
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End point description:

Anti-HPV antibodies were measured by the direct virus-like particle (VLP) electrochemiluminescence multi-plex immunoassay for detection of antibodies towards HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. Titers were expressed in terms of 1/dilution. Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, 'n'=subjects with available data for each specified category.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-vaccination)

Notes:

[18] - 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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	149	147		
Units: titers				
geometric mean (confidence interval 95%)				
Anti-HPV type-6: Day 31 (n=147,147)	2.30 (1.94 to 2.73)	2.03 (1.74 to 2.37)		
Anti-HPV type-6: Day 61 (n=149,147)	73.9 (64.3 to 85.0)	64.8 (55.8 to 75.4)		
Anti-HPV type-11: Day 31 (n=147,147)	1.11 (1.05 to 1.18)	1.08 (1.03 to 1.13)		
Anti-HPV type-11: Day 61 (n=149,147)	43.9 (38.9 to 49.5)	39.3 (33.9 to 45.5)		
Anti-HPV type-16: Day 31 (n=147,147)	2.06 (1.95 to 2.17)	2.08 (1.97 to 2.19)		
Anti-HPV type-16: Day 61 (n=149,147)	199 (171 to 231)	168 (142 to 199)		
Anti-HPV type-18: Day 31 (n=147,147)	1.59 (1.50 to 1.70)	1.52 (1.49 to 1.54)		
Anti-HPV type-18: Day 61 (n=149,147)	46.5 (38.4 to 56.4)	38.5 (31.3 to 47.4)		

Anti-HPV type-31: Day 31 (n=147,147)	1.08 (0.995 to 1.18)	1.05 (1.01 to 1.10)		
Anti-HPV type-31: Day 61 (n=149,147)	31.7 (26.5 to 38.1)	28.9 (24.0 to 34.9)		
Anti-HPV type-33: Day 31 (n=147,147)	1.01 (0.987 to 1.04)	1.02 (0.997 to 1.04)		
Anti-HPV type-33: Day 61 (n=149,147)	21.1 (17.8 to 24.9)	19.1 (16.1 to 22.7)		
Anti-HPV type-45: Day 31 (n=147,147)	0.520 (0.499 to 0.543)	0.509 (0.492 to 0.527)		
Anti-HPV type-45: Day 61 (n=149,147)	11.5 (9.35 to 14.1)	9.54 (7.68 to 11.9)		
Anti-HPV type-52: Day 31 (n=147,147)	0.535 (0.503 to 0.569)	0.514 (0.498 to 0.530)		
Anti-HPV type-52: Day 61 (n=149,147)	47.4 (41.1 to 54.7)	39.3 (33.5 to 46.1)		
Anti-HPV type-58: Day 31 (n=147,147)	1.09 (1.02 to 1.16)	1.05 (1.00 to 1.10)		
Anti-HPV type-58: Day 61 (n=149,147)	29.6 (25.5 to 34.3)	26.0 (22.2 to 30.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine: Group 3

End point title	Geometric Mean Titers (GMTs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine: Group 3 ^[19]
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End point description:

Anti-HPV antibodies were measured by the direct VLP electrochemiluminescence multi-plex immunoassay for detection of antibodies towards HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. Titers were expressed in terms of 1/dilution. Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC. Here, '-9999' and '99999' was used as a space fillers and denotes that 95% CI was not computable as the standard deviation of the sample was 0, since all subjects had the same value.

End point type	Secondary
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End point timeframe:

Day 01 (pre-vaccination) and Day 31 (post-vaccination)

Notes:

[19] - 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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: titers				
geometric mean (confidence interval 95%)				

Anti-HPV type-6: Day 01	2.12 (1.76 to 2.55)			
Anti-HPV type-6: Day 31	50.6 (42.0 to 60.9)			
Anti-HPV type-11: Day 01	1.07 (1.02 to 1.13)			
Anti-HPV type-11: Day 31	36.3 (30.8 to 42.8)			
Anti-HPV type-16: Day 01	2.02 (1.98 to 2.07)			
Anti-HPV type-16: Day 31	146 (118 to 179)			
Anti-HPV type-18: Day 01	1.50 (-9999 to 99999)			
Anti-HPV type-18: Day 31	31.2 (24.0 to 40.6)			
Anti-HPV type-31: Day 01	1.07 (1.02 to 1.13)			
Anti-HPV type-31: Day 31	24.7 (19.2 to 31.8)			
Anti-HPV type-33: Day 01	1.01 (0.989 to 1.03)			
Anti-HPV type-33: Day 31	15.0 (12.2 to 18.6)			
Anti-HPV type-45: Day 01	0.524 (0.493 to 0.556)			
Anti-HPV type-45: Day 31	8.24 (6.30 to 10.8)			
Anti-HPV type-52: Day 01	0.521 (0.500 to 0.544)			
Anti-HPV type-52: Day 31	40.9 (33.5 to 49.8)			
Anti-HPV type-58: Day 01	1.08 (1.02 to 1.14)			
Anti-HPV type-58: Day 31	20.6 (16.9 to 25.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers Ratios (GMTRs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine in Groups 1 and 2

End point title	Geometric Mean Titers Ratios (GMTRs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine in Groups 1 and 2 ^[20]
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End point description:

Anti-HPV antibodies were measured by the direct VLP electrochemiluminescence multi-plex immunoassay for detection of antibodies towards HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GMTRs were calculated as the ratio of GMTs at Day 61/Day 31. Blood samples were assessed for subjects at Day 31 and at Day 61, respectively. Analysis was performed on PPASC. Here, "number of subjects analysed" signifies subjects with available data for this endpoint.

End point type	Secondary
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End point timeframe:

Day 31 (post-vaccination) and Day 61 (post-vaccination)

Notes:

[20] - 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: Data is reported for all applicable arms in the study.

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	147		
Units: ratio				
geometric mean (confidence interval 95%)				
Anti-HPV type-6	32.0 (26.5 to 38.6)	31.9 (26.5 to 38.5)		
Anti-HPV type-11	39.0 (34.2 to 44.5)	36.5 (31.3 to 42.7)		
Anti-HPV type-16	96.6 (83.4 to 112)	80.8 (68.1 to 95.8)		
Anti-HPV type-18	29.7 (24.4 to 36.2)	25.4 (20.6 to 31.2)		
Anti-HPV type-31	29.8 (25.1 to 35.4)	27.5 (22.8 to 33.2)		
Anti-HPV type-33	20.8 (17.7 to 24.4)	18.7 (15.8 to 22.2)		
Anti-HPV type-45	21.9 (17.9 to 26.9)	18.8 (15.1 to 23.3)		
Anti-HPV type-52	88.0 (77.1 to 100)	76.5 (65.0 to 90.1)		
Anti-HPV type-58	27.1 (23.3 to 31.4)	24.8 (21.2 to 29.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers Ratios (GMTRs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine: Group 3

End point title	Geometric Mean Titers Ratios (GMTRs) of Antibodies Against Antigens Contained in Human Papillomavirus (HPV) Vaccine: Group 3 ^[21]
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End point description:

Anti-HPV antibodies were measured by the direct VLP electrochemiluminescence multi-plex immunoassay for detection of antibodies towards HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GMTRs were calculated as the ratio of GMTs at Day 31/Day 01. Blood samples were assessed for subjects at Day 01 and at Day 31, respectively. Analysis was performed on PPASC.

End point type	Secondary
End point timeframe:	
Day 01 (pre-vaccination) and Day 31 (post-vaccination)	

Notes:

[21] - 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: Data is reported for all applicable arms in the study.

End point values	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)			
Subject group type	Reporting group			
Number of subjects analysed	113			
Units: ratio				
geometric mean (confidence interval 95%)				
Anti-HPV type-6	23.9 (19.4 to 29.3)			
Anti-HPV type-11	33.9 (28.6 to 40.1)			
Anti-HPV type-16	71.9 (58.6 to 88.2)			
Anti-HPV type-18	20.8 (16.0 to 27.1)			
Anti-HPV type-31	23.1 (17.9 to 29.6)			
Anti-HPV type-33	14.9 (12.0 to 18.4)			
Anti-HPV type-45	15.7 (12.0 to 20.7)			
Anti-HPV type-52	78.4 (64.3 to 95.5)			
Anti-HPV type-58	19.1 (15.8 to 23.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroconversion Against Antigens Contained in Human Papillomavirus (HPV) Vaccine

End point title	Percentage of Subjects With Vaccine Seroconversion Against Antigens Contained in Human Papillomavirus (HPV) Vaccine
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End point description:

Vaccine Seroconversion was defined as changing serostatus from seronegative (subjects with a titer inferior to the serostatus cut-off value) at Baseline to seropositive after vaccination. A subject with a titer at or above the serostatus cut-off for a given HPV type was considered seropositive for that type. The serostatus cut-offs for HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 are 9, 6, 5, 5, 3, 4, 3, 5 and 5 milli-Merck units (mMU)/mL, respectively. Post vaccine seroconversion for antigens contained in HPV vaccine was Day 31 for Group 3 and Day 61 for Groups 1 and 2. Analysis was performed on PPASC. Here, 'number of subjects analysed' = subjects with available data for this endpoint.

End point type	Secondary
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End point timeframe:

Day 61 (post-vaccination for Groups 1 and 2) and Day 31 (post-vaccination for Group 3)

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	147	147	113	
Units: percentage of subjects				
number (confidence interval 95%)				
Anti-HPV type-6	87.8 (81.3 to 92.6)	88.4 (82.1 to 93.1)	85.0 (77.0 to 91.0)	
Anti-HPV type-11	99.3 (96.3 to 100)	97.3 (93.2 to 99.3)	97.3 (92.4 to 99.4)	
Anti-HPV type-16	99.3 (96.3 to 100)	96.6 (92.2 to 98.9)	98.2 (93.8 to 99.8)	
Anti-HPV type-18	94.6 (89.6 to 97.6)	92.5 (87.0 to 96.2)	88.5 (81.1 to 93.7)	
Anti-HPV type-31	96.6 (92.2 to 98.9)	93.2 (87.8 to 96.7)	88.5 (81.1 to 93.7)	
Anti-HPV type-33	95.2 (90.4 to 98.1)	91.8 (86.2 to 95.7)	87.6 (80.1 to 93.1)	
Anti-HPV type-45	81.6 (74.4 to 87.5)	83.0 (75.9 to 88.7)	75.2 (66.2 to 82.9)	
Anti-HPV type-52	99.3 (96.3 to 100)	98.0 (94.2 to 99.6)	96.5 (91.2 to 99.0)	
Anti-HPV type-58	95.2 (90.4 to 98.1)	92.5 (87.0 to 96.2)	92.0 (85.4 to 96.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Immediate Unsolicited Adverse Events (AEs)

End point title	Number of Subjects Reporting Immediate Unsolicited Adverse Events (AEs)
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End point description:

An AE was any untoward medical occurrence in a patient or in a clinical investigation subject administered a medicinal product and which did not have any causal relationship with the treatment. An unsolicited AE was an observed AE that did not fulfill the conditions prelisted in the case report form (CRF) in terms of diagnosis and/or onset window post-vaccination. All subjects were observed for 30 minutes after vaccination, and any unsolicited AEs occurred during that time were recorded as immediate unsolicited AEs in the CRF. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set that included all subjects who had received at least one dose of the study vaccines and had any safety data available. Here, 'n'=subjects with available data for each specified category and "n=0 and 99999 (a space filler)" in the number analysed field signifies that at Day 31, subjects of Group 3 received no vaccination.

End point type	Secondary
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End point timeframe:

Within 30 minutes post-any and each vaccination (Vaccination 1 [i.e., at Day 1] and 2 [i.e., at Day 31])

End point values	Group1:MenACYW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap- IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	171	171	116	
Units: subjects				
Post-any vaccination (n=171,171,116)	0	0	0	
Post-vaccination 1 (n=171,171,116)	0	0	0	
Post-vaccination 2 (n=169,168,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Solicited Injection Site Reactions

End point title	Number of Subjects Reporting Solicited Injection Site Reactions
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End point description:

SR: expected AR (sign or symptom) observed & reported under conditions (nature & onset) prelisted (i.e., solicited) in CRF and considered as related to product administered. Injection site reactions: pain, erythema, and swelling. Safety set. Here, 'n'=subjects with available data for specified category and "n=0" for MenACYW categories signifies no subjects were evaluable as in Group (Gps.)2 MenACYW vaccine was not administered; for Gps.1&3:"n=0" for Nimenrix categories signifies no subjects were evaluable as in Gps.1 & 3 Nimenrix was not administered. At Vaccination (vac.)1(Gps.1 & 2): "n=0"for 9vHPV & Tdap-IPV signifies no subjects were evaluable as these vaccines were not administered at vac.1 (D01). At Vacc2 (Gps.1, 2 & 3):"n=0" for MenACYW and Nimenrix signifies no subjects were evaluable as these vaccines were not administered at vacc.2(D31);for Gps. 3 "n=0" for 9vHPV and Tdap-IPV signifies no subjects were evaluable as these vaccines were not administered. "99999"=space filler.

End point type	Secondary
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End point timeframe:

Within 7 days post-any and each vaccination (Vaccination 1 [i.e., at Day 1] and 2 [i.e., at Day 31])

End point values	Group1:MenACYW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap- IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	171	171	116	
Units: subjects				
MenACYW: Pain: Post-any vacc. (n=169,0,116)	91	99999	69	
MenACYW: Erythema: Post-any vacc. (n=169,0,116)	19	99999	11	

MenACYW: Swelling: Post-any vacc. (n=169,0,116)	17	99999	12	
Nimenrix: Pain: Post-any vacc. (n=0,170,0)	99999	87	99999	
Nimenrix: Erythema: Post-any vacc. (n=0,170,0)	99999	3	99999	
Nimenrix: Swelling: Post-any vacc. (n=0,170,0)	99999	7	99999	
9vHPV: Pain: Post-any vacc. (n=168,165,116)	113	125	97	
9vHPV: Erythema: Post-any vacc. (n=168,165,116)	7	3	6	
9vHPV: Swelling: Post-any vacc. (n=168,165,116)	4	3	7	
Tdap-IPV: Pain: Post-any vacc. (n=168,164,116)	116	117	95	
Tdap-IPV: Erythema: Post-any vacc. (n=168,164,116)	9	5	13	
Tdap-IPV: Swelling: Post-any vacc. (n=168,164,116)	9	3	10	
MenACYW: Pain: Post-vacc. 1 (n=169,0,116)	91	99999	69	
MenACYW: Erythema: Post-vacc. 1 (n=169,0,116)	19	99999	11	
MenACYW: Swelling: Post-vacc. 1 (n=169,0,116)	17	99999	12	
Nimenrix: Pain: Post-vacc. 1 (n=0,170,0)	99999	87	99999	
Nimenrix: Erythema: Post-vacc. 1 (n=0,170,0)	99999	3	99999	
Nimenrix: Swelling: Post-vacc. 1 (n=0,170,0)	99999	7	99999	
9vHPV: Pain: Post-vacc. 1 (n=0,0,116)	99999	99999	97	
9vHPV: Erythema: Post-vacc. 1 (n=0,0,116)	99999	99999	6	
9vHPV: Swelling: Post-vacc. 1 (n=0,0,116)	99999	99999	7	
Tdap-IPV: Pain: Post-vacc. 1 (n=0,0,116)	99999	99999	95	
Tdap-IPV: Erythema: Post-vacc. 1 (n=0,0,116)	99999	99999	13	
Tdap-IPV: Swelling: Post-vacc. 1 (n=0,0,116)	99999	99999	10	
MenACYW: Pain: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
MenACYW: Erythema: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
MenACYW: Swelling: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
Nimenrix: Pain: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
Nimenrix: Erythema: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
Nimenrix: Swelling: Post-vacc. 2 (n=0,0,0)	99999	99999	99999	
9vHPV: Pain: Post-vacc. 2 (n=168,165,0)	113	125	99999	
9vHPV: Erythema: Post-vacc. 2 (n=168,165,0)	7	3	99999	
9vHPV: Swelling: Post-vacc. 2 (n=168,165,0)	4	3	99999	
Tdap-IPV: Pain: Post-vacc. 2 (n=168,164,0)	116	117	99999	

Tdap-IPV: Erythema: Post-vacc. 2 (n=168,164,0)	9	5	99999	
Tdap-IPV: Swelling: Post-vacc. 2 (n=168,164,0)	9	3	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Solicited Systemic Reactions

End point title	Number of Subjects Reporting Solicited Systemic Reactions
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End point description:

A solicited reaction was an expected adverse reaction (sign or symptom) observed and reported under the conditions (nature and onset) prelisted (i.e., solicited) in the CRF and considered as related to the product administered. Solicited systemic reactions included fever, headache, malaise, and myalgia. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set. Here, 'number of subjects analysed' = subjects with available data for this endpoint. Here, 'n' = subjects with available data for each specified category and "n=0" and 99999 (a space filler) signifies that at Day 31, subjects of Group 3 received no vaccination.

End point type	Secondary
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End point timeframe:

Within 7 days post-any and each vaccination (Vaccination 1 [i.e., at Day 1] and 2 [i.e., at Day 31])

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequ entially)	Group 2: Nimenrix® + 9vHPV + Tdap- IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Conco mitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	169	170	116	
Units: subjects				
Fever: Post-any vaccination (n=169,170,116)	12	11	6	
Headache: Post-any vaccination (n=169,170,116)	75	64	52	
Malaise: Post-any vaccination (n=169,170,116)	65	48	42	
Myalgia: Post-any vaccination (n=169,170,116)	84	81	67	
Fever: Post-vaccination 1 (n=169,170,116)	7	4	6	
Headache: Post-vaccination 1 (n=168,170,116)	59	44	52	
Malaise: Post-vaccination 1 (n=169,170,116)	46	32	42	
Myalgia: Post-vaccination 1 (n=169,170,116)	51	53	67	
Fever: Post-vaccination 2 (n=168,165,0)	6	7	99999	
Headache: Post-vaccination 2 (n=168,165,0)	37	40	99999	

Malaise: Post-vaccination 2 (n=168,165,0)	40	26	99999	
Myalgia: Post-vaccination 2 (n=168,165,0)	67	61	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Unsolicited Adverse Events (AEs)

End point title	Number of Subjects Reporting Unsolicited Adverse Events (AEs)
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End point description:

An AE was any untoward medical occurrence in a patient or in a clinical investigation subject administered a medicinal product and which did not had any casual relationship with the treatment. An unsolicited AE was an observed AE that did not fulfill the conditions prelisted in the CRF in terms of diagnosis and/or onset window post-vaccination. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set. Here, 'n' = subjects with available data for each specified category and "n=0" and 99999 (a space filler) signifies that at Day 31, subjects of Group 3 received no vaccination.

End point type	Secondary
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End point timeframe:

From Day 01 up to Day 31 post-any and each vaccination (Vaccination 1 [i.e., at Day 1] and 2 [i.e., at Day 31])

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Concomitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	171	171	116	
Units: subjects				
Post-any vaccination (n=171,171,116)	69	49	37	
Post-vaccination 1 (n=171,171,116)	49	31	37	
Post-vaccination 2 (n=169,168,0)	34	27	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Serious Adverse Events (SAEs) Including Adverse Events of Special Interest (AESI)

End point title	Number of Subjects Reporting Serious Adverse Events (SAEs) Including Adverse Events of Special Interest (AESI)
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End point description:

A SAE was any untoward medical occurrence that at any dose resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or

significant disability/incapacity, was a congenital anomaly/birth defect, or was an important medical event. A SAE which caused death of the subject was considered as fatal SAE. Adverse events of special interest (AESIs) were defined as event for which ongoing monitoring and rapid communication by the investigator to the sponsor was done. Reported AEs for each arm were presented as pre-specified in the study protocol. Analysis was performed on safety analysis set.

End point type	Secondary
End point timeframe:	
From Day 01 up to the last study day (i.e., Day 61 for Groups 1 and 2 and Day 31 for Group 3)	

End point values	Group1:MenAC YW Conjugate+9v HPV+Tdap-IPV Vaccines(Sequ entially)	Group 2: Nimenrix® + 9vHPV + Tdap- IPV Vaccines (Sequentially)	Group3:MenAC YW Conjugate+9v HPV+TdapIPV Vaccines(Conco mitantly)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	171	171	116	
Units: subjects				
SAE	0	1	0	
AESI	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited AE data: from Day 01 up to Day 31 post-any vaccination. SR data were collected from Day 01 up to Day 7 post-any vaccination. The SAEs were collected up to the last study day i.e., Day 61 for Groups 1 and 2 and Day 31 for Group 3

Adverse event reporting additional description:

SR: expected AR that was prelisted in CRF and considered to be related to vaccination. Unsolicited AE: observed AE that did not fulfill the conditions prelisted in CRF (i.e., solicited). Safety analysis set. In AE section, SR Fever is reported under Pyrexia. Reported AEs for each arm were presented as pre-specified in study protocol.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Group1:MenACYW Conjugate+9vHPV+Tdap-IPV Vaccines(Sequentially)
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Reporting group description:

Subjects received 0.5 mL intramuscular injection of MenACYW Conjugate vaccine on Day 01 and 0.5-mL intramuscular injection of 9vHPV + Tdap-IPV vaccines (sequentially after MenACYW vaccine) at Day 31.

Reporting group title	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)
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Reporting group description:

Subjects received 0.5 mL intramuscular injection of Nimenrix® vaccine on Day 01 and 0.5-mL intramuscular injection of 9vHPV + Tdap-IPV vaccines (sequentially after Nimenrix® vaccine) at Day 31.

Reporting group title	Group3:MenACYW Conjugate+9vHPV+TdapIPV Vaccines(Concomitantly)
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Reporting group description:

Subjects received 0.5 mL intramuscular injection of MenACYW Conjugate vaccine concomitantly with 9vHPV + Tdap-IPV vaccines on Day 01.

Serious adverse events	Group1:MenACYW Conjugate+9vHPV+ Tdap-IPV Vaccines(Sequentially)	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9vHPV+ TdapIPV Vaccines(Concomita
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 171 (0.00%)	1 / 171 (0.58%)	0 / 116 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Metabolism and nutrition disorders			
Type 1 Diabetes Mellitus			
subjects affected / exposed	0 / 171 (0.00%)	1 / 171 (0.58%)	0 / 116 (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

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

Non-serious adverse events	Group1:MenACYW Conjugate+9vHPV+ Tdap-IPV Vaccines(Sequentiall	Group 2: Nimenrix® + 9vHPV + Tdap-IPV Vaccines (Sequentially)	Group3:MenACYW Conjugate+9vHPV+ TdapIPV Vaccines(Concomita
Total subjects affected by non-serious adverse events			
subjects affected / exposed	153 / 171 (89.47%)	151 / 171 (88.30%)	112 / 116 (96.55%)
Nervous system disorders			
Headache			
subjects affected / exposed	76 / 171 (44.44%)	66 / 171 (38.60%)	52 / 116 (44.83%)
occurrences (all)	98	87	52
General disorders and administration site conditions			
Injection Site Swelling			
subjects affected / exposed	25 / 171 (14.62%)	13 / 171 (7.60%)	15 / 116 (12.93%)
occurrences (all)	30	13	30
Injection Site Bruising			
subjects affected / exposed	7 / 171 (4.09%)	9 / 171 (5.26%)	3 / 116 (2.59%)
occurrences (all)	8	10	3
Pyrexia			
subjects affected / exposed	14 / 171 (8.19%)	11 / 171 (6.43%)	6 / 116 (5.17%)
occurrences (all)	15	11	6
Injection Site Pain			
subjects affected / exposed	144 / 171 (84.21%)	140 / 171 (81.87%)	107 / 116 (92.24%)
occurrences (all)	320	329	261
Injection Site Erythema			
subjects affected / exposed	27 / 171 (15.79%)	9 / 171 (5.26%)	18 / 116 (15.52%)
occurrences (all)	35	11	30
Malaise			
subjects affected / exposed	65 / 171 (38.01%)	48 / 171 (28.07%)	42 / 116 (36.21%)
occurrences (all)	86	58	42
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	84 / 171 (49.12%)	81 / 171 (47.37%)	67 / 116 (57.76%)
occurrences (all)	118	114	67
Infections and infestations			

Covid-19 subjects affected / exposed occurrences (all)	9 / 171 (5.26%) 9	1 / 171 (0.58%) 1	2 / 116 (1.72%) 2
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 May 2020	Following changes were implemented: The third observational objective and the respective endpoints have been reclassified as secondary ones; countries in which the study was conducted were updated; removed the cross in the column "Collection of information in the CRF" for the item "Review of temporary contraindications for blood sampling"; blood samples labeling updated per Operating Guidelines in Tables 8.1 and 8.2; classification of 9vHPV and Tdap-IPV vaccines modified from NIMP to IMP. These vaccines were referred as co-administered vaccines; wording adjustment to provide more clarity about the assent Form and inform consent form signing; Inclusion criterion #10 modified (split into two) and a new exclusion criterion #23 created; the right classification of 9vHPV and Tdap-IPV vaccines were IMP according to STD-000017 (i.e., co-administered products); to complement information about Tdap-IPV; to update information regarding the IMPs' batch numbers used; concomitant therapy definition was updated; in the event of a local or national immunization program with a pandemic influenza vaccine, COVID-19 vaccine or any other vaccine as needed, subjects who received the vaccine mentioned above at any time during the study were not withdrawn from the study; blood samples labelling in Tables 8.1 and 8.2 had been updated as per the Operational guidelines; the definition of Safety analysis set, FAS & PPAS were updated to clarify populations used for the statistical analyses and be homogeneous with other MenACYW conjugate studies; minor changes to be homogeneous with other MenACYW conjugate studies from the program; new section created to provide information about the impact of the COVID-19 pandemic in statistical analysis; section 10.3.1 created to incorporate list of contraceptive methods.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported