Clinical trial results:
Immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Infants and Toddlers When Administered Using a 1+1 Schedule in a National Immunization Schedule Having a Meningococcal Group B Vaccine as Standard of Care

Summary

EudraCT number	2017-004520-30
Trial protocol	GB
Global end of trial date	05 December 2022

Results information

Result version number	v1 (current)
This version publication date	22 October 2023
First version publication date	22 October 2023

Trial information

Trial identification

Sponsor protocol code	MET52

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03632720
WHO universal trial number (UTN)	U1111-1183-6530

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	Discovery Drive, Swiftwater, United States, PA, 18370-0187
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)	Yes
EMA paediatric investigation plan number(s)	EMEA-001930-PIP01-16
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	19 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 December 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 antibody responses to meningococcal serogroups A, C, Y and W in terms of serum bactericidal assay using human complement (hSBA) vaccine seroprotection (antibody titer greater than or equal to [>=] 1:8) when Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus toxoid (MenACYW) Conjugate vaccine was administered concomitantly with Bexsero® in the second year of life compared to when MenACYW Conjugate vaccine is given alone.

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 were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 788
Worldwide total number of subjects	788
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	788
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:

Study was conducted at 16 sites in the United Kingdom from 10 October 2018 to 05 December 2022.

Pre-assignment

Screening details:

A total of 788 subjects were enrolled and randomised in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenACYW Conjugate Vaccine + Bexsero®

Arm description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

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

Dosage and administration details:

Subjects received MenACYW Conjugate vaccine 0.5 millilitre (mL) intramuscular (IM) injection at the age of 3 months and at the age of 12 to 13 months.

Investigational medicinal product name	Meningococcal group B vaccine
Investigational medicinal product code	
Other name	Bexsero®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Bexsero® vaccine 0.5 mL IM injection at the age of 2, 4 and 12 to 13 months.

Investigational medicinal product name	Diphtheria, tetanus, pertussis (acellular component), hepatitis B, poliomyelitis (inactivated) vaccine
Investigational medicinal product code	
Other name	Infanrix hexa®
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Infanrix hexa® vaccine 0.5 mL IM injection at the age of 2, 3 and 4 months.

Investigational medicinal product name	Human rotavirus vaccine
Investigational medicinal product code	
Other name	Rotarix®
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Rotarix® vaccine 1.5 mL oral suspension at the age of 2 and 3 months.

Investigational medicinal product name	Pneumococcal 13-valent polysaccharide Conjugate vaccine
Investigational medicinal product code	
Other name	Prevenar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Prevenar 13® vaccine 0.5 mL IM injection at the age of 2 and 4 months.

Arm title	Group 2: MenACYW Conjugate Vaccine + Bexsero®

Arm description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2 and 4 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

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

Dosage and administration details:

Subjects received MenACYW Conjugate vaccine 0.5 mL IM injection at the age of 3 months and at the age of 12 to 13 months.

Investigational medicinal product name	Meningococcal group B vaccine
Investigational medicinal product code	
Other name	Bexsero®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Bexsero® vaccine 0.5 mL IM injection at the age of 2 and 4 months.

Investigational medicinal product name	Diphtheria, tetanus, pertussis (acellular component), hepatitis B, poliomyelitis (inactivated) vaccine
Investigational medicinal product code	
Other name	Infanrix hexa®
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Infanrix hexa® vaccine 0.5 mL IM injection at the age of 2, 3 and 4 months.

Investigational medicinal product name	Human rotavirus vaccine
Investigational medicinal product code	
Other name	Rotarix®
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Rotarix® vaccine 1.5 mL oral suspension at the age of 2 and 3 months.

Investigational medicinal product name	Pneumococcal 13-valent polysaccharide Conjugate vaccine
Investigational medicinal product code	
Other name	Prevenar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Prevenar 13® vaccine 0.5 mL IM injection at the age of 2 and 4 months.

Arm title	Group 3: Bexsero®

Arm description:

Subjects aged 2 months (at the time of enrollment) received Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Meningococcal group B vaccine
Investigational medicinal product code	
Other name	Bexsero®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Bexsero® vaccine 0.5 mL IM injection at the age of 2, 4 and 12 to 13 months.

Investigational medicinal product name	Diphtheria, tetanus, pertussis (acellular component), hepatitis B, poliomyelitis (inactivated) vaccine
Investigational medicinal product code	
Other name	Infanrix hexa®
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Infanrix hexa® vaccine 0.5 mL IM injection at the age of 2, 3 and 4 months.

Investigational medicinal product name	Human rotavirus vaccine
Investigational medicinal product code	
Other name	Rotarix®
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

Subjects received Rotarix® vaccine 1.5 mL oral suspension at the age of 2 and 3 months.

Investigational medicinal product name	Pneumococcal 13-valent polysaccharide Conjugate vaccine
Investigational medicinal product code	
Other name	Prevenar 13®
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received Prevenar 13® vaccine 0.5 mL IM injection at the age of 2 and 4 months.

Number of subjects in period 1	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®
Started	314	316	158
Safety Analysis Set	314	314	157
Completed	301	305	150
Not completed	13	11	8
Adverse Event	2	-	-

Withdrawal by parent/legal representative	11	9	8
Screen failure	-	1	-
Lost to follow-up	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenACYW Conjugate Vaccine + Bexsero®
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.	
Reporting group title	Group 2: MenACYW Conjugate Vaccine + Bexsero®
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2 and 4 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.	
Reporting group title	Group 3: Bexsero®
Reporting group description:	
Subjects aged 2 months (at the time of enrollment) received Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.	

Reporting group values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®
Number of subjects	314	316	158
Age categorical Units: Subjects			
Age continuous Units: days			
arithmetic mean	64.7	63.9	64.8
standard deviation	± 6.88	± 6.73	± 7.03
Gender categorical Units: Subjects			
Female	148	154	81
Male	166	161	77
Missing	0	1	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	4	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	0
White	300	296	148
More than one race	4	10	4
Unknown or Not Reported	9	4	2

Reporting group values	Total		
Number of subjects	788		

Age categorical Units: Subjects			

Age continuous Units: days arithmetic mean standard deviation	- -		
Gender categorical Units: Subjects			
Female	383		
Male	404		
Missing	1		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	9		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	2		
White	744		
More than one race	18		
Unknown or Not Reported	15		

End points

End points reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine + Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Reporting group title	Group 2: MenACYW Conjugate Vaccine + Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2 and 4 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Reporting group title	Group 3: Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Primary: Percentage of Subjects With Antibody Titers Greater Than or Equal to (>=) 1:8 Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA After Vaccination: Groups 1 and 2 - PPAS3

End point title	Percentage of Subjects With Antibody Titers Greater Than or Equal to (>=) 1:8 Against Meningococcal Serogroups A, C, Y, and W Measured by hSBA After Vaccination: Groups 1 and 2 - PPAS3[1]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by serum bactericidal assay using human complement (hSBA) assay. Percentage of subjects with antibody titers greater than or equal to (>=)1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Data for this endpoint was not planned to be collected and analysed for Group 3. Analysis was performed on Per-Protocol Analysis Set 3 (PPAS3) defined for accessing ACYW immune response data for subjects who received at least 1 dose of study vaccine and had valid post-vaccination serology results of 2nd year of life, with no relevant protocol deviation. Here, 'n' = subjects with available data for each specified category.

End point type	Primary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	169		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=159,156)	100 (97.7 to 100)	99.4 (96.5 to 100)		

Serogroup C (n=168,165)	100 (97.8 to 100)	100 (97.8 to 100)		
Serogroup Y (n=161,159)	100 (97.7 to 100)	100 (97.7 to 100)		
Serogroup W (n=172,160)	99.4 (96.8 to 100)	100 (97.7 to 100)		

Statistical analyses

Statistical analysis title	Serogroup A
Statistical analysis description:	
Group 1: MenACYW Conjugate Vaccine + Bexsero® (2, 4, and 12 to 13 Months) versus Group 2: MenACYW Conjugate Vaccine + Bexsero® (2 and 4 Months)	
Comparison groups	Group 1: MenACYW Conjugate Vaccine + Bexsero® v Group 2: MenACYW Conjugate Vaccine + Bexsero®
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in Percentage
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.78
upper limit	3.54

Notes:

[2] - The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95 percent (%) confidence interval (CI) was greater (>) -10% for all four serogroups.

Statistical analysis title	Serogroup C
Statistical analysis description:	
Group 1: MenACYW Conjugate Vaccine + Bexsero® (2, 4, and 12 to 13 Months) versus Group 2: MenACYW Conjugate Vaccine + Bexsero® (2 and 4 Months)	
Comparison groups	Group 1: MenACYW Conjugate Vaccine + Bexsero® v Group 2: MenACYW Conjugate Vaccine + Bexsero®
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.24
upper limit	2.28

Notes:

[3] - The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was > -10% for all four serogroups.

Statistical analysis title	Serogroup Y
Statistical analysis description:	
Group 1: MenACYW Conjugate Vaccine + Bexsero® (2, 4, and 12 to 13 Months) versus Group 2: MenACYW Conjugate Vaccine + Bexsero® (2 and 4 Months)	

Comparison groups	Group 1: MenACYW Conjugate Vaccine + Bexsero® v Group 2: MenACYW Conjugate Vaccine + Bexsero®
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.33
upper limit	2.36

Notes:

[4] - The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was > -10% for all four serogroups.

Statistical analysis title	Serogroup W

Statistical analysis description:

Group 1: MenACYW Conjugate Vaccine + Bexsero® (2, 4, and 12 to 13 Months) versus Group 2: MenACYW Conjugate Vaccine + Bexsero® (2 and 4 Months)

Comparison groups	Group 1: MenACYW Conjugate Vaccine + Bexsero® v Group 2: MenACYW Conjugate Vaccine + Bexsero®
Number of subjects included in analysis	347
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in Percentage
Point estimate	-0.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.22
upper limit	1.81

Notes:

[5] - The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was > -10% for all four serogroups.

Secondary: Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Geometric Mean Titers (GMTs) of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[6]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS3. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	169		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=159,156)	1214 (993 to 1484)	205 (168 to 250)		
Serogroup C (n=168,165)	963 (784 to 1182)	744 (608 to 911)		
Serogroup Y (n=161,159)	454 (374 to 551)	434 (359 to 525)		
Serogroup W (n=172,160)	578 (478 to 698)	528 (439 to 635)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1

End point title	Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1[7]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Infancy was defined as up to 4 months of age. Titers were expressed in terms of 1/dilution. Data for this endpoint was not planned to be collected and analysed for Group 3. Analysis was performed on per-protocol analysis set 1 (PPAS1) defined for accessing ACYW immune response data for subjects who received at least 1 dose of study vaccine and had valid post-vaccination serology result of infancy (up to 4 months age) vaccination stage, with no relevant protocol deviations. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=22,27)	8.52 (5.16 to 14.1)	7.22 (4.39 to 11.9)		

Serogroup C (n=27,34)	3.70 (2.84 to 4.84)	3.84 (2.49 to 5.92)		
Serogroup Y (n=27,30)	3.26 (2.23 to 4.76)	2.58 (2.17 to 3.07)		
Serogroup W (n=24,29)	2.52 (1.93 to 3.30)	2.15 (1.98 to 2.33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[8]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Infancy was defined as up to 4 months of age. Titers were expressed in terms of 1/dilution. Data for this endpoint was not planned to be collected and analysed for Group 3. Analysis was performed PPAS1. Here, 'n' = subjects with available data for each specified category.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=64,71)	10.8 (8.40 to 14.0)	9.63 (7.46 to 12.4)		
Serogroup C (n=77,77)	78.0 (52.9 to 115)	61.2 (41.3 to 90.7)		
Serogroup Y (n=71,68)	9.44 (7.16 to 12.5)	6.33 (4.93 to 813)		
Serogroup W (n=76,73)	4.67 (3.74 to 5.83)	3.81 (3.12 to 4.66)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3

End point title	Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3[9]

End point description:

GMTs of antibodies against meningococcal serogroups A, C, Y, and W were measured by hSBA. Infancy was defined as up to 4 months of age. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	26		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=31,26)	45.8 (28.4 to 73.8)	22.6 (13.5 to 37.9)		
Serogroup C (n=35,26)	30.2 (19.0 to 47.9)	8.44 (5.18 to 13.7)		
Serogroup Y (n=32,26)	25.2 (16.8 to 37.8)	9.90 (6.43 to 15.3)		
Serogroup W (n=35,26)	34.6 (21.4 to 56.1)	10.4 (6.58 to 16.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[10]

End point description:

GMTs of antibodies against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS3. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	169		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=159,156)	1214 (993 to 1484)	205 (168 to 250)		
Serogroup C (n=168,165)	963 (784 to 1182)	744 (608 to 911)		
Serogroup Y (n=161,159)	454 (374 to 551)	434 (359 to 525)		
Serogroup W (n=172,160)	578 (478 to 698)	528 (439 to 635)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1

End point title	Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1[11]

End point description:

GMTs of antibodies against meningococcal serogroups A, C, Y, and W were measured by serum bactericidal assay using baby rabbit complement (rSBA). Infancy was defined as up to 4 months of age. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. '-99999' and '99999' are used as space filler and denote that 95 percent (%) confidence interval (CI) was not computable as the standard deviation (SD) of the sample was 0, since all subjects had the same value. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=16,22)	2.00 (-99999 to 99999)	2.00 (-99999 to 99999)		
Serogroup C (n=19,23)	2.88 (1.84 to 4.52)	3.77 (2.01 to 7.04)		
Serogroup Y (n=19,23)	2.68 (1.76 to 4.08)	2.70 (1.87 to 3.92)		
Serogroup W (n=17,23)	2.89 (1.69 to 4.94)	2.00 (-99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[12]

End point description:

GMTs of antibodies against meningococcal serogroups A, C, Y, and W were measured by rSBA. Infancy was defined as up to 4 months of age. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=36,32)	13.7 (6.89 to 27.3)	20.7 (9.96 to 43.2)		
Serogroup C (n=38,32)	251 (147 to 430)	347 (230 to 523)		

Serogroup Y (n=36,25)	152 (84.2 to 275)	124 (56.3 to 276)		
Serogroup W (n=36,30)	87.1 (41.1 to 185)	50.8 (19.4 to 133)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3

End point title	Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3[13]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. '-99999' and '99999' are used as space filler an denote that 95% CI was not computable as the sample size was too small to compute valid data. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=6,5)	32.0 (1.20 to 855)	169 (-99999 to 99999)		
Serogroup C (n=7,5)	58.0 (18.6 to 181)	3.48 (-99999 to 99999)		
Serogroup Y (n=7,5)	58.0 (6.82 to 493)	6.96 (-99999 to 99999)		
Serogroup W (n=5,5)	8.00 (-99999 to 99999)	8.00 (-99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[14]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	54		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A (n=47,43)	1741 (1354 to 2240)	1508 (1073 to 2118)		
Serogroup C (n=47,43)	1396 (1047 to 1860)	1532 (1061 to 2212)		
Serogroup Y (n=45,43)	2620 (1999 to 3435)	1414 (997 to 2005)		
Serogroup W (n=46,43)	2491 (1852 to 3351)	2566 (1780 to 3700)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1[15]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.4 and >=1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:4 (n=22,27)	81.8 (59.7 to 94.8)	74.1 (53.7 to 88.9)		
Serogroup A: >= 1:8 (n=22,27)	59.1 (36.4 to 79.3)	48.1 (28.7 to 68.1)		
Serogroup C: >= 1:4 (n=27,34)	55.6 (35.3 to 74.5)	38.2 (22.2 to 56.4)		
Serogroup C: >= 1:8 (n=27,34)	25.9 (11.1 to 46.3)	20.6 (8.7 to 37.9)		
Serogroup Y: >= 1:4 (n=27,30)	29.6 (13.8 to 50.2)	26.7 (12.3 to 45.9)		
Serogroup Y: >= 1:8 (n=27,30)	22.2 (8.6 to 42.3)	10.0 (2.1 to 26.5)		
Serogroup W: >= 1:4 (n=24,29)	16.7 (4.7 to 37.4)	10.3 (2.2 to 27.4)		
Serogroup W: >= 1:8 (n=24,29)	8.3 (1.0 to 27.0)	0 (0 to 11.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[16]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.4 and >=1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:4 (n=64,71)	87.5 (76.8 to 94.4)	85.9 (75.6 to 93.0)		
Serogroup A: >= 1:8 (n=64,71)	73.4 (60.9 to 83.7)	66.2 (54.0 to 77.0)		
Serogroup C: >= 1:4 (n=77,77)	93.5 (85.5 to 97.9)	90.9 (82.2 to 96.3)		
Serogroup C: >= 1:8 (n=77,77)	87.0 (77.4 to 93.6)	88.3 (79.0 to 94.5)		
Serogroup Y: >= 1:4 (n=71,68)	81.7 (70.7 to 89.9)	69.1 (56.7 to 79.8)		
Serogroup Y: >= 1:8 (n=71,68)	66.2 (54.0 to 77.0)	54.4 (41.9 to 66.5)		
Serogroup W: >= 1:4 (n=76,73)	56.6 (44.7 to 67.9)	46.6 (34.8 to 58.6)		
Serogroup W: >= 1:8 (n=76,73)	35.5 (24.9 to 47.3)	27.4 (17.6 to 39.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3[17]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.4 and >=1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	26		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:4 (n=31,26)	100 (88.8 to 100)	96.2 (80.4 to 99.9)		
Serogroup A: >= 1:8 (n=31,26)	93.5 (78.6 to 99.2)	76.9 (56.4 to 91.0)		
Serogroup C: >= 1:4 (n=35,26)	94.3 (80.8 to 99.3)	73.1 (52.2 to 88.4)		
Serogroup C: >= 1:8 (n=35,26)	85.7 (69.7 to 95.2)	53.8 (33.4 to 73.4)		
Serogroup Y: >= 1:4 (n=32,26)	96.9 (83.8 to 99.9)	88.5 (69.8 to 97.6)		
Serogroup Y: >= 1:8 (n=32,26)	93.8 (79.2 to 99.2)	73.1 (52.2 to 88.4)		
Serogroup W: >= 1:4 (n=35,26)	97.1 (85.1 to 99.9)	84.6 (65.1 to 95.6)		
Serogroup W: >= 1:8 (n=35,26)	88.6 (73.3 to 96.8)	69.2 (48.2 to 85.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[18]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with antibody titers >=1.4 and >=1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	169		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:4 (n=159,156)	100 (97.7 to 100)	100 (97.7 to 100)		
Serogroup A: >= 1:8 (n=159,156)	100 (97.7 to 100)	99.4 (96.5 to 100)		
Serogroup C: >= 1:4 (n=168,165)	100 (97.8 to 100)	100 (97.8 to 100)		
Serogroup C: >= 1:8 (n=168,165)	100 (97.8 to 100)	100 (97.8 to 100)		
Serogroup Y: >= 1:4 (n=161,159)	100 (97.7 to 100)	100 (97.7 to 100)		
Serogroup Y: >= 1:8 (n=161,159)	100 (97.7 to 100)	100 (97.7 to 100)		
Serogroup W: >= 1:4 (n=172,160)	99.4 (96.8 to 100)	100 (97.7 to 100)		
Serogroup W: >= 1:8 (n=172,160)	99.4 (96.8 to 100)	100 (97.7 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS1[19]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.8 and >=1:128 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:8 (n=16,22)	0 (0 to 20.6)	0 (0 to 15.4)		
Serogroup A: >= 1:128 (n=16,22)	0 (0 to 20.6)	0 (0 to 15.4)		
Serogroup C: >= 1:8 (n=19,23)	15.8 (3.4 to 39.6)	17.4 (5.0 to 38.8)		
Serogroup C: >= 1:128 (n=19,23)	0 (0 to 17.6)	4.3 (0.1 to 21.9)		
Serogroup Y: >= 1:8 (n=19,23)	10.5 (1.3 to 33.1)	13.0 (2.8 to 33.6)		
Serogroup Y: >= 1:128 (n=19,23)	0 (0 to 17.6)	0 (0 to 14.8)		
Serogroup W: >= 1:8 (n=17,23)	11.8 (1.5 to 36.4)	0 (0 to 14.8)		
Serogroup W: >= 1:128 (n =17,23)	0 (0 to 19.5)	0 (0 to 14.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[20]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.8 and >=1:128 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: percentage of subjects				

number (confidence interval 95%)				
Serogroup A: >= 1:8 (n=36,32)	52.8 (35.5 to 69.6)	65.6 (46.8 to 81.4)		
Serogroup A: >= 1:128 (n=36,32)	19.4 (8.2 to 36.0)	28.1 (13.7 to 46.7)		
Serogroup C: >= 1:8 (n=38,32)	97.4 (86.2 to 99.9)	100 (89.1 to 100)		
Serogroup C: >= 1:128 (n=38,32)	78.9 (62.7 to 90.4)	96.9 (83.8 to 99.9)		
Serogroup Y: >= 1:8 (n=36,25)	91.7 (77.5 to 98.2)	92.0 (74.0 to 99.0)		
Serogroup Y: >= 1:128 (n=36,25)	80.6 (64.0 to 91.8)	68.0 (46.5 to 85.1)		
Serogroup W: >= 1:8 (n=36,30)	77.8 (60.8 to 89.9)	63.3 (43.9 to 80.1)		
Serogroup W: >= 1:128 (n=36,30)	75.0 (57.8 to 87.9)	53.3 (34.3 to 71.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W Before Vaccination: Group 1 and 2 - PPAS3[21]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with antibody titers >=1.8 and >=1:128 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:8 (n=6,5)	50.0 (11.8 to 88.2)	80.0 (28.4 to 99.5)		
Serogroup A: >= 1:128 (n=6,5)	50.0 (11.8 to 88.2)	80.0 (28.4 to 99.5)		

Serogroup C: >= 1:8 (n=7,5)	100 (59.0 to 100)	20.0 (0.5 to 71.6)		
Serogroup C: >= 1:128 (n=7,5)	42.9 (9.9 to 81.6)	0 (0 to 52.2)		
Serogroup Y: >= 1:8 (n=7,5)	85.7 (42.1 to 99.6)	40.0 (5.3 to 85.3)		
Serogroup Y: >= 1:128 (n=7,5)	28.6 (3.7 to 71.0)	0 (0 to 52.2)		
Serogroup W: >= 1:8 (n=5,5)	40.0 (5.3 to 85.3)	60.0 (14.7 to 94.7)		
Serogroup W: >= 1:128 (n=5,5)	20.0 (0.5 to 71.6)	0 (0 to 52.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[22]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Percentage of subjects with antibody titers >=1.8 and >=1:128 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[22] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	54		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A: >= 1:8 (n=47,43)	100 (92.5 to 100)	100 (91.8 to 100)		
Serogroup A: >= 1:128 (n=47,43)	100 (92.5 to 100)	97.7 (87.7 to 99.9)		
Serogroup C: >= 1:8 (n=47,43)	100 (92.5 to 100)	100 (91.8 to 100)		
Serogroup C: >= 1:128 (n=47,43)	100 (92.5 to 100)	100 (91.8 to 100)		
Serogroup Y: >= 1:8 (n=45,43)	100 (92.1 to 100)	100 (91.8 to 100)		

Serogroup Y: >= 1:128 (n=45,43)	100 (92.1 to 100)	97.7 (87.7 to 99.9)		
Serogroup W: >= 1:8 (n=46,43)	100 (92.3 to 100)	100 (91.8 to 100)		
Serogroup W: >= 1:128 (n=46,43)	100 (92.3 to 100)	97.7 (87.7 to 99.9)		

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 After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With >= 4-Fold Rise in hSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[23]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 3 months) to pre-dose titer at the age of 3 months. Infancy was defined as up to 4 months of age. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months, 30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

Notes:

[23] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=17,24)	5.9 (0.1 to 28.7)	25.0 (9.8 to 46.7)		
Serogroup C (n=27,34)	70.4 (49.8 to 86.2)	82.4 (65.5 to 93.2)		
Serogroup Y (n=24,26)	45.8 (25.6 to 67.2)	53.8 (33.4 to 73.4)		
Serogroup W (n=24,27)	29.2 (12.6 to 51.1)	18.5 (6.3 to 38.1)		

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 After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With >= 4-Fold Rise in hSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[24]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 12 to 13 months) to pre-dose titer before vaccination at the age of 3 months. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months, 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[24] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	32		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=22,24)	100 (84.6 to 100)	91.7 (73.0 to 99.0)		
Serogroup C (N=28,32)	92.9 (76.5 to 99.1)	93.8 (79.2 to 99.2)		
Serogroup Y (n=27,29)	96.3 (81.0 to 99.9)	100 (88.1 to 100)		
Serogroup W (n=26,26)	100 (86.8 to 100)	100 (86.8 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 After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With >= 4-Fold Rise in hSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[25]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 12 to 13

months) to pre-dose titer before vaccination at the age of 12 to 13 months. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months, 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[25] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	26		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=27,26)	100 (87.2 to 100)	53.8 (33.4 to 73.4)		
Serogroup C (n=33,26)	100 (89.4 to 100)	100 (86.8 to 100)		
Serogroup Y (n=29,25)	89.7 (72.6 to 97.8)	96.0 (79.6 to 99.9)		
Serogroup W (n=34,25)	85.3 (68.9 to 95.0)	100 (86.3 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[26]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 3 months) to pre-dose titer at the age of 3 months. Infancy was defined as up to 4 months of age. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months, 30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

Notes:

[26] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=13,16)	46.2 (19.2 to 74.9)	62.5 (35.4 to 84.8)		
Serogroup C (n=15,16)	86.7 (59.5 to 98.3)	87.5 (61.7 to 98.4)		
Serogroup Y (n=14,11)	78.6 (49.2 to 95.3)	90.9 (58.7 to 99.8)		
Serogroup W (n=14,15)	57.1 (28.9 to 82.3)	53.3 (26.6 to 78.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[27]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 12 to 13 months) to pre-dose titer before vaccination at the age of 3 months. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months, 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[27] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	54		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=13,17)	100 (75.3 to 100)	100 (80.5 to 100)		
Serogroup C (n=17,17)	100 (80.5 to 100)	100 (80.5 to 100)		
Serogroup Y (n=16,17)	100 (79.4 to 100)	100 (80.5 to 100)		
Serogroup W (n=15,17)	100 (78.2 to 100)	100 (80.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With >= 4-Fold Rise in rSBA Antibody Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[28]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Fold-rise was calculated as ratio of post-vaccination titer (i.e., 30 days post-vaccination at the age of 12 to 13 months) to pre-dose titer before vaccination at the age of 12 to 13 months. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months, 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[28] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=6,5)	83.3 (35.9 to 99.6)	100 (47.8 to 100)		

Serogroup C (n=7,5)	100 (59.0 to 100)	100 (47.8 to 100)		
Serogroup Y (n=7,5)	71.4 (29.0 to 96.3)	100 (47.8 to 100)		
Serogroup W (n=5,5)	100 (47.8 to 100)	100 (47.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[29]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titer >=1:16 for subjects with pre-vaccination hSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Infancy was defined as up to 4 months of age. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months up to 30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

Notes:

[29] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	78	77		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=17,24)	0 (0 to 19.5)	20.8 (7.1 to 42.2)		
Serogroup C (n=27,34)	66.7 (46.0 to 83.5)	79.4 (62.1 to 91.3)		
Serogroup Y (n=24,26)	33.3 (15.6 to 55.3)	30.8 (14.3 to 51.8)		
Serogroup W (n=24,27)	25.0 (9.8 to 46.7)	11.1 (2.4 to 29.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[30]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titer >=1:16 for subjects with pre-vaccination hSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months up to 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[30] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	28	32		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=22,24)	100 (84.6 to 100)	91.7 (73.0 to 99.0)		
Serogroup C (n=28,32)	92.9 (76.5 to 99.1)	93.8 (79.2 to 99.2)		
Serogroup Y (n=27,29)	96.3 (81.0 to 99.9)	96.6 (82.2 to 99.9)		
Serogroup W (n=26,26)	100 (86.8 to 100)	100 (86.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[31]

End point description:

The hSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination hSBA titer >=1:16 for subjects with pre-vaccination hSBA titer <1:8 or at least a 4-fold increase in

hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months up to 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[31] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	26		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=27,26)	100 (87.2 to 100)	53.8 (33.4 to 73.4)		
Serogroup C (n=33,26)	100 (89.4 to 100)	96.2 (80.4 to 99.9)		
Serogroup Y (n=29,25)	89.7 (72.6 to 97.8)	96.0 (79.6 to 99.9)		
Serogroup W (n=34,25)	85.3 (68.9 to 95.0)	100 (86.3 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS1[32]

End point description:

The rSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination rSBA titer >=1:32 for subjects with pre-vaccination rSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Infancy was defined as up to 4 months of age. Analysis was performed on PPAS1. Here, 'subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months up to 30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

Notes:

[32] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	51		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=13,16)	30.8 (9.1 to 61.4)	50.0 (24.7 to 75.3)		
Serogroup C (n=15,16)	86.7 (59.5 to 98.3)	87.5 (61.7 to 98.4)		
Serogroup Y (n=14,11)	71.4 (41.9 to 91.6)	72.7 (39.0 to 94.0)		
Serogroup W (n=14,15)	57.1 (28.9 to 82.3)	53.3 (26.6 to 78.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[33]

End point description:

The rSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination rSBA titer >=1:32 for subjects with pre-vaccination rSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months up to 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[33] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	54		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=13,17)	100 (75.3 to 100)	100 (80.5 to 100)		
Serogroup C (n=17,17)	100 (80.5 to 100)	100 (80.5 to 100)		
Serogroup Y (n=16,17)	100 (79.4 to 100)	94.1 (71.3 to 99.9)		
Serogroup W (n=15,17)	100 (78.2 to 100)	100 (80.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3

End point title	Percentage of Subjects With Vaccine Seroresponse Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W After Vaccination: Group 1 and 2 - PPAS3[34]

End point description:

The rSBA vaccine seroresponse against serogroups A, C, Y, and W was defined as post-vaccination rSBA titer >=1:32 for subjects with pre-vaccination rSBA titer <1:8 or at least a 4-fold increase in hSBA titers from pre to post-vaccination for subjects with pre-vaccination hSBA titers >=1:8. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months up to 30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

Notes:

[34] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	5		
Units: percentage of subjects				
number (confidence interval 95%)				
Serogroup A (n=6,5)	83.3 (35.9 to 99.6)	100 (47.8 to 100)		

Serogroup C (n=7,5)	100 (59.0 to 100)	100 (47.8 to 100)		
Serogroup Y (n=7,5)	71.4 (29.0 to 96.3)	100 (47.8 to 100)		
Serogroup W (n=5,5)	100 (47.8 to 100)	100 (47.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS1

End point title	Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS1

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with hSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category and '99999' is used as space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	77	84	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=22,27,29)	18.2	25.9	24.1	
Serogroup A: >=1:4 (n=22,27,29)	81.8	74.1	75.9	
Serogroup A: >=1:8 (n=22,27,29)	59.1	48.1	48.3	
Serogroup A: >=1:16 (n=22,27,29)	36.4	33.3	27.6	
Serogroup A: >=1:32 (n=22,27,29)	22.7	11.1	20.7	
Serogroup A: >=1:64 (n=22,27,29)	4.5	7.4	10.3	
Serogroup A: >=1:128 (n=22,27,29)	4.5	7.4	3.4	
Serogroup A: >=1:256 (n=22,27,0)	0	3.7	99999	
Serogroup A: >=1:512 (n=22,27,0)	0	0	99999	
Serogroup A: >=1:1024 (n=22,27,0)	0	0	99999	
Serogroup C: <1:4 (n=27,34,35)	44.4	61.8	62.9	
Serogroup C: >=1:4 (n=27,34,35)	55.6	38.2	37.1	
Serogroup C: >=1:8 (n=27,34,35)	25.9	20.6	14.3	
Serogroup C: >=1:16 (n=27,34,35)	7.4	11.8	11.4	
Serogroup C: >=1:32 (n=27,34,35)	0	5.9	2.9	

Serogroup C: >=1:64 (n=27,34,35)	0	5.9	2.9	
Serogroup C: >=1:128 (n=27,34,35)	0	5.9	0	
Serogroup C: >=1:256 (n=27,34,0)	0	2.9	99999	
Serogroup C: >=1:512 (n=27,34,0)	0	2.9	99999	
Serogroup C: >=1:1024 (n=27,34,0)	0	0	99999	
Serogroup Y: <1:4 (n=27,30,33)	70.4	73.3	84.8	
Serogroup Y: >=1:4 (n=27,30,33)	29.6	26.7	15.2	
Serogroup Y: >=1:8 (n=27,30,33)	22.2	10.0	12.1	
Serogroup Y: >=1:16 (n=27,30,33)	7.4	0	3.0	
Serogroup Y: >=1:32 (n=27,30,33)	3.7	0	0	
Serogroup Y: >=1:64 (n=27,30,33)	3.7	0	0	
Serogroup Y: >=1:128 (n=27,30,33)	3.7	0	0	
Serogroup Y: >=1:256 (n=27,30,0)	0	0	99999	
Serogroup Y: >=1:512 (n=27,30,0)	0	0	99999	
Serogroup Y: >=1:1024 (n=27,30,0)	0	0	99999	
Serogroup W: <1:4 (n=24,29,32)	83.3	89.7	87.5	
Serogroup W: >=1:4 (n=24,29,32)	16.7	10.3	12.5	
Serogroup W: >=1:8 (n=24,29,32)	8.3	0	3.1	
Serogroup W: >=1:16 (n=24,29,32)	4.2	0	3.1	
Serogroup W: >=1:32 (n=24,29,32)	4.2	0	3.1	
Serogroup W: >=1:64 (n=24,29,32)	0	0	0	
Serogroup W: >=1:128 (n=24,29,32)	0	0	0	
Serogroup W: >=1:256 (n=24,29,0)	0	0	99999	
Serogroup W: >=1:512 (n=24,29,0)	0	0	99999	
Serogroup W: >=1:1024 (n=24,29,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS1

End point title	Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS1

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with hSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'n' = subjects with available data for each specified category and '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	77	84	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=64,71,66)	12.5	14.1	21.2	
Serogroup A: >=1:4 (n=64,71,66)	87.5	85.9	78.8	
Serogroup A: >=1:8 (n=64,71,66)	73.4	66.2	51.5	
Serogroup A: >=1:16 (n=64,71,66)	51.6	42.3	34.8	
Serogroup A: >=1:32 (n=64,71,66)	21.9	19.7	16.7	
Serogroup A: >=1:64 (n=64,71,66)	7.8	9.9	9.1	
Serogroup A: >=1:128 (n=64,71,66)	1.6	2.8	3.0	
Serogroup A: >=1:256 (n=64,71,0)	0	0	99999	
Serogroup A: >=1:512 (n=64,71,0)	0	0	99999	
Serogroup A: >=1:1024 (n=64,71,0)	0	0	99999	
Serogroup C: <1:4 (n=77,77,84)	6.5	9.1	78.6	
Serogroup C: >=1:4 (n=77,77,84)	93.5	90.9	21.4	
Serogroup C: >=1:8 (n=77,77,84)	87.0	88.3	7.1	
Serogroup C: >=1:16 (n=77,77,84)	85.7	80.5	6.0	
Serogroup C: >=1:32 (n=77,77,84)	81.8	71.4	3.6	
Serogroup C: >=1:64 (n=77,77,84)	66.2	66.2	1.2	
Serogroup C: >=1:128 (n=77,77,84)	54.5	49.4	0	
Serogroup C: >=1:256 (n=77,77,0)	32.5	28.6	99999	
Serogroup C: >=1:512 (n=77,77,0)	20.8	13.0	99999	
Serogroup C: >=1:1024 (n=77,77,0)	6.5	5.2	99999	
Serogroup Y: <1:4 (n=71,68,73)	18.3	30.9	89.0	
Serogroup Y: >=1:4 (n=71,68,73)	81.7	69.1	11.0	
Serogroup Y: >=1:8 (n=71,68,73)	66.2	54.4	2.7	
Serogroup Y: >=1:16 (n=71,68,73)	40.8	25.0	2.7	
Serogroup Y: >=1:32 (n=71,68,73)	21.1	11.8	1.4	
Serogroup Y: >=1:64 (n=71,68,73)	7.0	4.4	1.4	
Serogroup Y: >=1:128 (n=71,68,73)	4.2	1.5	0	
Serogroup Y: >=1:256 (n=71,68,0)	1.4	0	99999	
Serogroup Y: >=1:512 (n=71,68,0)	1.4	0	99999	
Serogroup Y: >=1:1024 (n=71,68,0)	0	0	99999	
Serogroup W: <1:4 (n=76,73,77)	43.4	53.4	94.8	
Serogroup W: >=1:4 (n=76,73,77)	56.6	46.6	5.2	
Serogroup W: >=1:8 (n=76,73,77)	35.5	27.4	2.6	
Serogroup W: >=1:16 (n=76,73,77)	21.1	13.7	1.3	
Serogroup W: >=1:32 (n=76,73,77)	5.3	4.1	0	
Serogroup W: >=1:64 (n=76,73,77)	2.6	1.4	0	
Serogroup W: >=1:128 (n=76,73,77)	1.3	0	0	
Serogroup W: >=1:256 (n=76,73,0)	0	0	99999	
Serogroup W: >=1:512 (n=76,73,0)	0	0	99999	
Serogroup W: >=1:1024 (n=76,73,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS3

End point title	Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS3

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with hSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192; >=1:16384; >=1:32768; >=1:65536 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Here, '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	26	35	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=31,26,34)	0	3.8	11.8	
Serogroup A: >=1:4 (n=31,26,34)	100	96.2	88.2	
Serogroup A: >=1:8 (n=31,26,34)	93.5	76.9	73.5	
Serogroup A: >=1:16 (n=31,26,34)	90.3	73.1	55.9	
Serogroup A: >=1:32 (n=31,26,34)	64.5	61.5	41.2	
Serogroup A: >=1:64 (n=31,26,34)	48.4	23.1	29.4	
Serogroup A: >=1:128 (n=31,26,34)	29.0	15.4	23.5	
Serogroup A: >=1:256 (n=31,26,34)	22.6	3.8	5.9	
Serogroup A: >=1:512 (n=31,26,34)	3.2	0	2.9	
Serogroup A: >=1:1024 (n=31,26,34)	0	0	0	
Serogroup A: >=1:2048 (n=31,26,34)	0	0	0	
Serogroup A: >=1:4096 (n=31,26,34)	0	0	0	
Serogroup A: >=1:8192 (n=31,26,34)	0	0	0	
Serogroup A: >=1:16384 (n=31,26,34)	0	0	0	
Serogroup A: >=1:32768 (n=31,26,34)	0	0	0	
Serogroup A: >=1:65536 (n=0,0,34)	99999	99999	0	
Serogroup C: <1:4 (n=35,26,35)	5.7	26.9	94.3	
Serogroup C: >=1:4 (n=35,26,35)	94.3	73.1	5.7	
Serogroup C: >=1:8 (n=35,26,35)	85.7	53.8	0	
Serogroup C: >=1:16 (n=35,26,35)	71.4	42.3	0	
Serogroup C: >=1:32 (n=35,26,35)	65.7	34.6	0	
Serogroup C: >=1:64 (n=35,26,35)	48.6	3.8	0	

Serogroup C: >=1:128 (n=35,26,35)	20.0	0	0	
Serogroup C: >=1:256 (n=35,26,35)	5.7	0	0	
Serogroup C: >=1:512 (n=35,26,35)	0	0	0	
Serogroup C: >=1:1024 (n=35,26,35)	0	0	0	
Serogroup C: >=1:2048 (n=35,26,35)	0	0	0	
Serogroup C: >=1:4096 (n=35,26,35)	0	0	0	
Serogroup C: >=1:8192 (n=35,26,35)	0	0	0	
Serogroup C: >=1:16384 (n=35,26,35)	0	0	0	
Serogroup C: >=1:32768 (n=35,26,35)	0	0	0	
Serogroup C: >=1:65536 (n=0,0,35)	99999	99999	0	
Serogroup Y: <1:4 (n=32,26,35)	3.1	11.5	94.3	
Serogroup Y: >=1:4 (n=32,26,35)	96.9	88.5	5.7	
Serogroup Y: >=1:8 (n=32,26,35)	93.8	73.1	5.7	
Serogroup Y: >=1:16 (n=32,26,35)	78.1	34.6	2.9	
Serogroup Y: >=1:32 (n=32,26,35)	50.0	19.2	2.9	
Serogroup Y: >=1:64 (n=32,26,35)	28.1	11.5	2.9	
Serogroup Y: >=1:128 (n=32,26,35)	12.5	3.8	2.9	
Serogroup Y: >=1:256 (n=32,26,35)	6.3	0	2.9	
Serogroup Y: >=1:512 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:1024 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:2048 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:4096 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:8192 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:16384 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:32768 (n=32,26,35)	0	0	0	
Serogroup Y: >=1:65536 (n=0,0,35)	99999	99999	0	
Serogroup W: <1:4 (n=35,26,35)	2.9	15.4	100	
Serogroup W: >=1:4 (n=35,26,35)	97.1	84.6	0	
Serogroup W: >=1:8 (n=35,26,35)	88.6	69.2	0	
Serogroup W: >=1:16 (n=35,26,35)	77.1	46.2	0	
Serogroup W: >=1:32 (n=35,26,35)	60.0	23.1	0	
Serogroup W: >=1:64 (n=35,26,35)	45.7	11.5	0	
Serogroup W: >=1:128 (n=35,26,35)	28.6	3.8	0	
Serogroup W: >=1:256 (n=35,26,35)	8.6	0	0	
Serogroup W: >=1:512 (n=35,26,35)	5.7	0	0	
Serogroup W: >=1:1024 (n=35,26,35)	0	0	0	
Serogroup W: >=1:2048 (n=35,26,35)	0	0	0	
Serogroup W: >=1:4096 (n=35,26,35)	0	0	0	
Serogroup W: >=1:8192 (n=35,26,35)	0	0	0	
Serogroup W: >=1:16384 (n=35,26,35)	0	0	0	
Serogroup W: >=1:32768 (n=35,26,35)	0	0	0	
Serogroup W: >=1:65536 (n=0,0,35)	99999	99999	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS3

End point title	Percentage of Subjects With Distribution of hSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS3

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with hSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192; >=1:16384; >=1:32768; >=1:65536 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'n' = subjects with available data for each specified category and '99999' is used as a space filler and denotes that no subjects had available data for the specified titer category.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	178	169	86	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=159,156,80)	0	0	0	
Serogroup A: >=1:4 (n=159,156,80)	100	100	100	
Serogroup A: >=1:8 (n=159,156,80)	100	99.4	100	
Serogroup A: >=1:16 (n=159,156,80)	100	98.7	100	
Serogroup A: >=1:32 (n=159,156,80)	100	94.2	97.5	
Serogroup A: >=1:64 (n=159,156,80)	99.4	87.2	93.8	
Serogroup A: >=1:128 (n=159,156,80)	97.5	75.0	90.0	
Serogroup A: >=1:256 (n=159,156,80)	94.3	58.3	83.8	
Serogroup A: >=1:512 (n=159,156,80)	83.6	35.3	76.3	
Serogroup A: >=1:1024 (n=159,156,80)	68.6	17.9	52.5	
Serogroup A: >=1:2048 (n=159,156,80)	39.0	1.9	26.3	
Serogroup A: >=1:4096 (n=159,156,80)	25.2	0	15.0	
Serogroup A: >=1:8192 (n=159,156,80)	10.1	0	5.0	
Serogroup A: >=1:16384 (n=159,156,80)	6.3	0	2.5	
Serogroup A: >=1:32768 (n=159,156,80)	0.6	0	1.3	
Serogroup A: >=1:65536 (n=0,0,80)	99999	99999	1.3	
Serogroup C: <1:4 (n=168,165,85)	0	0	10.6	
Serogroup C: >=1:4 (n=168,165,85)	100	100	89.4	
Serogroup C: >=1:8 (n=168,165,85)	100	100	78.8	
Serogroup C: >=1:16 (n=168,165,85)	99.4	99.4	69.4	
Serogroup C: >=1:32 (n=168,165,85)	98.2	99.4	56.5	
Serogroup C: >=1:64 (n=168,165,85)	97.6	98.2	30.6	
Serogroup C: >=1:128 (n=168,165,85)	95.2	92.7	22.4	
Serogroup C: >=1:256 (n=168,165,85)	90.5	86.1	7.1	

Serogroup C: >=1:512 (n=168,165,85)	78.6	73.3	4.7	
Serogroup C: >=1:1024 (n=168,165,85)	64.9	58.2	2.4	
Serogroup C: >=1:2048 (n=168,165,85)	35.7	25.5	0	
Serogroup C: >=1:4096 (n=168,165,85)	22.0	14.5	0	
Serogroup C: >=1:8192 (n=168,165,85)	8.3	5.5	0	
Serogroup C: >=1:16384 (n=168,165,85)	0.6	0.6	0	
Serogroup C: >=1:32768 (n=168,165,85)	0	0.6	0	
Serogroup C: >=1:65536 (n=0,0,85)	99999	99999	0	
Serogroup Y: <1:4 (n=161,159,82)	0	0	46.3	
Serogroup Y: >=1:4 (n=161,159,82)	100	100	53.7	
Serogroup Y: >=1:8 (n=161,159,82)	100	100	35.4	
Serogroup Y: >=1:16 (n=161,159,82)	99.4	99.4	23.2	
Serogroup Y: >=1:32 (n=161,159,82)	98.8	98.1	6.1	
Serogroup Y: >=1:64 (n=161,159,82)	94.4	95.6	0	
Serogroup Y: >=1:128 (n=161,159,82)	89.4	89.9	0	
Serogroup Y: >=1:256 (n=161,159,82)	77.6	81.1	0	
Serogroup Y: >=1:512 (n=161,159,82)	65.2	61.0	0	
Serogroup Y: >=1:1024 (n=161,159,82)	39.1	32.7	0	
Serogroup Y: >=1:2048 (n=161,159,82)	11.2	9.4	0	
Serogroup Y: >=1:4096 (n=161,159,82)	5.6	5.7	0	
Serogroup Y: >=1:8192 (n=161,159,82)	1.9	3.1	0	
Serogroup Y: >=1:16384 (n=161,159,82)	0	0	0	
Serogroup Y: >=1:32768 (n=161,159,82)	0	0	0	
Serogroup Y: >=1:65536 (n=0,0,82)	99999	99999	0	
Serogroup W: <1:4 (n=172,160,86)	0.6	0	96.5	
Serogroup W: >=1:4 (n=172,160,86)	99.4	100	3.5	
Serogroup W: >=1:8 (n=172,160,86)	99.4	100	2.3	
Serogroup W: >=1:16 (n=172,160,86)	98.8	99.4	0	
Serogroup W: >=1:32 (n=172,160,86)	98.3	98.8	0	
Serogroup W: >=1:64 (n=172,160,86)	98.3	98.1	0	
Serogroup W: >=1:128 (n=172,160,86)	93.6	93.1	0	
Serogroup W: >=1:256 (n=172,160,86)	84.9	85.0	0	
Serogroup W: >=1:512 (n=172,160,86)	70.3	64.4	0	
Serogroup W: >=1:1024 (n=172,160,86)	45.9	43.8	0	
Serogroup W: >=1:2048 (n=172,160,86)	15.7	13.1	0	
Serogroup W: >=1:4096 (n=172,160,86)	9.3	4.4	0	
Serogroup W: >=1:8192 (n=172,160,86)	2.3	1.9	0	
Serogroup W: >=1:16384 (n=172,160,86)	1.2	1.3	0	
Serogroup W: >=1:32768 (n=172,160,86)	0	1.3	0	
Serogroup W: >=1:65536 (n=0,0,86)	99999	99999	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS1

End point title	Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS1

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with rSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Here, '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 3 months

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	51	56	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=16,22,25)	100	100	100	
Serogroup A: >=1:4 (n=16,22,25)	0	0	0	
Serogroup A: >=1:8 (n=16,22,25)	0	0	0	
Serogroup A: >=1:16 (n=16,22,25)	0	0	0	
Serogroup A: >=1:32 (n=16,22,25)	0	0	0	
Serogroup A: >=1:64 (n=16,22,25)	0	0	0	
Serogroup A: >=1:128 (n=16,22,25)	0	0	0	
Serogroup A: >=1:256 (n=16,22,25)	0	0	0	
Serogroup A: >=1:512 (n=16,22,25)	0	0	0	
Serogroup A: >=1:1024 (n=16,22,25)	0	0	0	
Serogroup A: >=1:2048 (n=16,22,25)	0	0	0	
Serogroup A: >=1:4096 (n=16,22,0)	0	0	99999	
Serogroup A: >=1:8192 (n=16,22,0)	0	0	99999	
Serogroup C: <1:4 (n=19,23,26)	84.2	82.6	84.6	
Serogroup C: >=1:4 (n=19,23,26)	15.8	17.4	15.4	
Serogroup C: >=1:8 (n=19,23,26)	15.8	17.4	11.5	

Serogroup C: >=1:16 (n=19,23,26)	10.5	17.4	7.7	
Serogroup C: >=1:32 (n=19,23,26)	5.3	17.4	0	
Serogroup C: >=1:64 (n=19,23,26)	5.3	13.0	0	
Serogroup C: >=1:128 (n=19,23,26)	0	4.3	0	
Serogroup C: >=1:256 (n=19,23,26)	0	4.3	0	
Serogroup C: >=1:512 (n=19,23,26)	0	0	0	
Serogroup C: >=1:1024 (n=19,23,26)	0	0	0	
Serogroup C: >=1:2048 (n=19,23,26)	0	0	0	
Serogroup C: >=1:4096 (n=19,23,0)	0	0	99999	
Serogroup C: >=1:8192 (n=19,23,0)	0	0	99999	
Serogroup Y: <1:4 (n=19,23,26)	89.5	87.0	84.6	
Serogroup Y: >=1:4 (n=19,23,26)	10.5	13.0	15.4	
Serogroup Y: >=1:8 (n=19,23,26)	10.5	13.0	15.4	
Serogroup Y: >=1:16 (n=19,23,26)	10.5	8.7	7.7	
Serogroup Y: >=1:32 (n=19,23,26)	10.5	4.3	3.8	
Serogroup Y: >=1:64 (n=19,23,26)	0	4.3	3.8	
Serogroup Y: >=1:128 (n=19,23,26)	0	0	0	
Serogroup Y: >=1:256 (n=19,23,26)	0	0	0	
Serogroup Y: >=1:512 (n=19,23,26)	0	0	0	
Serogroup Y: >=1:1024 (n=19,23,26)	0	0	0	
Serogroup Y: >=1:2048 (n=19,23,26)	0	0	0	
Serogroup Y: >=1:4096 (n=19,23,0)	0	0	99999	
Serogroup Y: >=1:8192 (n=19,23,0)	0	0	99999	
Serogroup W: <1:4 (n=17,23,26)	88.2	100	96.2	
Serogroup W: >=1:4 (n=17,23,26)	11.8	0	3.8	
Serogroup W: >=1:8 (n=17,23,26)	11.8	0	3.8	
Serogroup W: >=1:16 (n=17,23,26)	11.8	0	3.8	
Serogroup W: >=1:32 (n=17,23,26)	11.8	0	3.8	
Serogroup W: >=1:64 (n=17,23,26)	5.9	0	3.8	
Serogroup W: >=1:128 (n=17,23,26)	0	0	0	
Serogroup W: >=1:256 (n=17,23,26)	0	0	0	
Serogroup W: >=1:512 (n=17,23,26)	0	0	0	
Serogroup W: >=1:1024 (n=17,23,26)	0	0	0	
Serogroup W: >=1:2048 (n=17,23,26)	0	0	0	
Serogroup W: >=1:4096 (n=17,23,0)	0	0	99999	
Serogroup W: >=1:8192 (n=17,23,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS1

End point title	Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS1

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with rSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192 for meningococcal serogroups A, C, Y, and W were reported in this endpoint.

Analysis was performed on PPAS1. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Here, '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months)

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	51	56	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=36,32,36)	38.9	21.9	97.2	
Serogroup A: >=1:4 (n=36,32,36)	61.1	78.1	2.8	
Serogroup A: >=1:8 (n=36,32,36)	52.8	65.6	0	
Serogroup A: >=1:16 (n=36,32,36)	44.4	53.1	0	
Serogroup A: >=1:32 (n=36,32,36)	41.7	43.8	0	
Serogroup A: >=1:64 (n=36,32,36)	36.1	31.3	0	
Serogroup A: >=1:128 (n=36,32,36)	19.4	28.1	0	
Serogroup A: >=1:256 (n=36,32,36)	8.3	21.9	0	
Serogroup A: >=1:512 (n=36,32,36)	5.6	9.4	0	
Serogroup A: >=1:1024 (n=36,32,36)	5.6	3.1	0	
Serogroup A: >=1:2048 (n=36,32,36)	2.8	3.1	0	
Serogroup A: >=1:4096 (n=36,32,0)	0	0	99999	
Serogroup A: >=1:8192 (n=36,32,0)	0	0	99999	
Serogroup C: <1:4 (n=38,32,37)	2.6	0	86.5	
Serogroup C: >=1:4 (n=38,32,37)	97.4	100	13.5	
Serogroup C: >=1:8 (n=38,32,37)	97.4	100	8.1	
Serogroup C: >=1:16 (n=38,32,37)	94.7	100	5.4	
Serogroup C: >=1:32 (n=38,32,37)	89.5	100	5.4	
Serogroup C: >=1:64 (n=38,32,37)	81.6	96.9	0	
Serogroup C: >=1:128 (n=38,32,37)	78.9	96.9	0	
Serogroup C: >=1:256 (n=38,32,37)	71.1	65.6	0	
Serogroup C: >=1:512 (n=38,32,37)	55.3	40.6	0	
Serogroup C: >=1:1024 (n=38,32,37)	23.7	28.1	0	
Serogroup C: >=1:2048 (n=38,32,37)	5.3	9.4	0	
Serogroup C: >=1:4096 (n=38,32,0)	2.6	3.1	99999	
Serogroup C: >=1:8192 (n=38,32,0)	0	3.1	99999	
Serogroup Y: <1:4 (n=36,25,31)	8.3	8.0	90.3	
Serogroup Y: >=1:4 (n=36,25,31)	91.7	92.0	9.7	
Serogroup Y: >=1:8 (n=36,25,31)	91.7	92.0	9.7	
Serogroup Y: >=1:16 (n=36,25,31)	88.9	88.0	9.7	
Serogroup Y: >=1:32 (n=36,25,31)	83.3	80.0	6.5	
Serogroup Y: >=1:64 (n=36,25,31)	80.6	72.0	3.2	
Serogroup Y: >=1:128 (n=36,25,31)	80.6	68.0	3.2	
Serogroup Y: >=1:256 (n=36,25,31)	63.9	48.0	3.2	
Serogroup Y: >=1:512 (n=36,25,31)	36.1	36.0	3.2	

Serogroup Y: >=1:1024 (n=36,25,31)	5.6	12.0	3.2	
Serogroup Y: >=1:2048 (n=36,25,31)	2.8	4.0	3.2	
Serogroup Y: >=1:4096 (n=36,25,0)	0	4.0	99999	
Serogroup Y: >=1:8192 (n=36,25,0)	0	0	99999	
Serogroup W: <1:4 (n=36,30,36)	22.2	33.3	100	
Serogroup W: >=1:4 (n=36,30,36)	77.8	66.7	0	
Serogroup W: >=1:8 (n=36,30,36)	77.8	63.3	0	
Serogroup W: >=1:16 (n=36,30,36)	77.8	63.3	0	
Serogroup W: >=1:32 (n=36,30,36)	75.0	63.3	0	
Serogroup W: >=1:64 (n=36,30,36)	75.0	63.3	0	
Serogroup W: >=1:128 (n=36,30,36)	75.0	53.3	0	
Serogroup W: >=1:256 (n=36,30,36)	50.0	50.0	0	
Serogroup W: >=1:512 (n=36,30,36)	19.4	26.7	0	
Serogroup W: >=1:1024 (n=36,30,36)	11.1	13.3	0	
Serogroup W: >=1:2048 (n=36,30,36)	5.6	3.3	0	
Serogroup W: >=1:4096 (n=36,30,0)	0	0	99999	
Serogroup W: >=1:8192 (n=36,30,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS3

End point title	Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W Before Vaccination - PPAS3

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Infancy was defined as up to 4 months of age. Percentage of subjects with rSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192; >=1:16384; >=1:32768 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Here, '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

Before vaccination at the age of 12 to 13 months

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	5	6	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=6,5,6)	50.0	20.0	50.0	

Serogroup A: >=1:4 (n=6,5,6)	50.0	80.0	50.0	
Serogroup A: >=1:8 (n=6,5,6)	50.0	80.0	50.0	
Serogroup A: >=1:16 (n=6,5,6)	50.0	80.0	50.0	
Serogroup A: >=1:32 (n=6,5,6)	50.0	80.0	50.0	
Serogroup A: >=1:64 (n=6,5,6)	50.0	80.0	50.0	
Serogroup A: >=1:128 (n=6,5,6)	50.0	80.0	33.3	
Serogroup A: >=1:256 (n=6,5,6)	33.3	60.0	33.3	
Serogroup A: >=1:512 (n=6,5,6)	33.3	40.0	33.3	
Serogroup A: >=1:1024 (n=6,5,6)	33.3	40.0	16.7	
Serogroup A: >=1:2048 (n=6,5,6)	0	20.0	16.7	
Serogroup A: >=1:4096 (n=6,5,6)	0	0	16.7	
Serogroup A: >=1:8192 (n=6,5,0)	0	0	99999	
Serogroup A: >=1:16384 (n=6,5,0)	0	0	99999	
Serogroup A: >=1:32768 (n=6,5,0)	0	0	99999	
Serogroup C: <1:4 (n=7,5,6)	0	80.0	100	
Serogroup C: >=1:4 (n=7,5,6)	100	20.0	0	
Serogroup C: >=1:8 (n=7,5,6)	100	20.0	0	
Serogroup C: >=1:16 (n=7,5,6)	85.7	20.0	0	
Serogroup C: >=1:32 (n=7,5,6)	71.4	20.0	0	
Serogroup C: >=1:64 (n=7,5,6)	71.4	0	0	
Serogroup C: >=1:128 (n=7,5,6)	42.9	0	0	
Serogroup C: >=1:256 (n=7,5,6)	14.3	0	0	
Serogroup C: >=1:512 (n=7,5,6)	0	0	0	
Serogroup C: >=1:1024 (n=7,5,6)	0	0	0	
Serogroup C: >=1:2048 (n=7,5,6)	0	0	0	
Serogroup C: >=1:4096 (n=7,5,6)	0	0	0	
Serogroup C: >=1:8192 (n=7,5,0)	0	0	99999	
Serogroup C: >=1:16384 (n=7,5,0)	0	0	99999	
Serogroup C: >=1:32768 (n=7,5,0)	0	0	99999	
Serogroup Y: <1:4 (n=7,5,6)	14.3	40.0	100	
Serogroup Y: >=1:4 (n=7,5,6)	85.7	60.0	0	
Serogroup Y: >=1:8 (n=7,5,6)	85.7	40.0	0	
Serogroup Y: >=1:16 (n=7,5,6)	85.7	40.0	0	
Serogroup Y: >=1:32 (n=7,5,6)	71.4	20.0	0	
Serogroup Y: >=1:64 (n=7,5,6)	57.1	20.0	0	
Serogroup Y: >=1:128 (n=7,5,6)	28.6	0	0	
Serogroup Y: >=1:256 (n=7,5,6)	14.3	0	0	
Serogroup Y: >=1:512 (n=7,5,6)	14.3	0	0	
Serogroup Y: >=1:1024 (n=7,5,6)	14.3	0	0	
Serogroup Y: >=1:2048 (n=7,5,6)	14.3	0	0	
Serogroup Y: >=1:4096 (n=7,5,6)	14.3	0	0	
Serogroup Y: >=1:8192 (n=7,5,0)	0	0	99999	
Serogroup Y: >=1:16384 (n=7,5,0)	0	0	99999	
Serogroup Y: >=1:32768 (n=7,5,0)	0	0	99999	
Serogroup W: <1:4 (n=5,5,6)	40.0	40.0	100	
Serogroup W: >=1:4 (n=5,5,6)	60.0	60.0	0	
Serogroup W: >=1:8 (n=5,5,6)	40.0	60.0	0	
Serogroup W: >=1:16 (n=5,5,6)	40.0	40.0	0	
Serogroup W: >=1:32 (n=5,5,6)	20.0	20.0	0	
Serogroup W: >=1:64 (n=5,5,6)	20.0	20.0	0	
Serogroup W: >=1:128 (n=5,5,6)	20.0	0	0	
Serogroup W: >=1:256 (n=5,5,6)	0	0	0	

Serogroup W: >=1:512 (n=5,5,6)	0	0	0	
Serogroup W: >=1:1024 (n=5,5,6)	0	0	0	
Serogroup W: >=1:2048 (n=5,5,6)	0	0	0	
Serogroup W: >=1:4096 (n=5,5,6)	0	0	0	
Serogroup W: >=1:8192 (n=5,5,0)	0	0	99999	
Serogroup W: >=1:16384 (n=5,5,0)	0	0	99999	
Serogroup W: >=1:32768 (n=5,5,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS3

End point title	Percentage of Subjects With Distribution of rSBA Titers Against Meningococcal Serogroups A, C, Y, and W After Vaccination - PPAS3

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Percentage of subjects with rSBA antibody titers distribution <1:4, >=1:4, >=1:8, >=1:16; >=1:32; >=1:64, >=1:128, >=1:256; >=1:512; >=1:1024; >=1:2048; >=1:4096; >=1:8192; >=1:16384; >=1:32768 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS3. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category. Here, '99999' is used as a space filler and denotes that no subject had available data for the specified titer category.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 12 to 13 months (i.e., at the age of 13 to 14 months)

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	54	54	52	
Units: percentage of subjects				
number (not applicable)				
Serogroup A: <1:4 (n=47,43,41)	0	0	14.6	
Serogroup A: >=1:4 (n=47,43,41)	100	100	85.4	
Serogroup A: >=1:8 (n=47,43,41)	100	100	85.4	
Serogroup A: >=1:16 (n=47,43,41)	100	100	85.4	
Serogroup A: >=1:32 (n=47,43,41)	100	100	85.4	
Serogroup A: >=1:64 (n=47,43,41)	100	100	85.4	
Serogroup A: >=1:128 (n=47,43,41)	100	97.7	85.4	
Serogroup A: >=1:256 (n=47,43,41)	100	97.7	75.6	
Serogroup A: >=1:512 (n=47,43,41)	97.9	88.4	68.3	
Serogroup A: >=1:1024 (n=47,43,41)	87.2	79.1	51.2	
Serogroup A: >=1:2048 (n=47,43,41)	53.2	51.2	36.6	
Serogroup A: >=1:4096 (n=47,43,41)	29.8	32.6	17.1	

Serogroup A: >=1:8192 (n=47,43,0)	6.4	9.3	99999	
Serogroup A: >=1:16384 (n=47,43,0)	2.1	0	99999	
Serogroup A: >=1:32768 (n=47,43,0)	0	0	99999	
Serogroup C: <1:4 (n=47,43,44)	0	0	88.6	
Serogroup C: >=1:4 (n=47,43,44)	100	100	11.4	
Serogroup C: >=1:8 (n=47,43,44)	100	100	11.4	
Serogroup C: >=1:16 (n=47,43,44)	100	100	11.4	
Serogroup C: >=1:32 (n=47,43,44)	100	100	11.4	
Serogroup C: >=1:64 (n=47,43,44)	100	100	11.4	
Serogroup C: >=1:128 (n=47,43,44)	100	100	9.1	
Serogroup C: >=1:256 (n=47,43,44)	100	95.3	0	
Serogroup C: >=1:512 (n=47,43,44)	89.4	88.4	0	
Serogroup C: >=1:1024 (n=47,43,44)	74.5	72.1	0	
Serogroup C: >=1:2048 (n=47,43,44)	51.1	53.5	0	
Serogroup C: >=1:4096 (n=47,43,44)	21.3	34.9	0	
Serogroup C: >=1:8192 (n=47,43,0)	8.5	9.3	99999	
Serogroup C: >=1:16384 (n=47,43,0)	0	4.7	99999	
Serogroup C: >=1:32768 (n=47,43,0)	0	0	99999	
Serogroup Y: <1:4 (n=45,43,43)	0	0	7.0	
Serogroup Y: >=1:4 (n=45,43,43)	100	100	93.0	
Serogroup Y: >=1:8 (n=45,43,43)	100	100	93.0	
Serogroup Y: >=1:16 (n=45,43,43)	100	100	93.0	
Serogroup Y: >=1:32 (n=45,43,43)	100	97.7	93.0	
Serogroup Y: >=1:64 (n=45,43,43)	100	97.7	93.0	
Serogroup Y: >=1:128 (n=45,43,43)	100	97.7	93.0	
Serogroup Y: >=1:256 (n=45,43,43)	100	95.3	90.7	
Serogroup Y: >=1:512 (n=45,43,43)	97.8	95.3	79.1	
Serogroup Y: >=1:1024 (n=45,43,43)	93.3	79.1	67.4	
Serogroup Y: >=1:2048 (n=45,43,43)	77.8	53.5	46.5	
Serogroup Y: >=1:4096 (n=45,43,43)	44.4	20.9	11.6	
Serogroup Y: >=1:8192 (n=45,43,0)	17.8	9.3	99999	
Serogroup Y: >=1:16384 (n=45,43,0)	2.2	0	99999	
Serogroup Y: >=1:32768 (n=45,43,0)	2.2	0	99999	
Serogroup W: <1:4 (n=46,43,42)	0	0	81.0	
Serogroup W: >=1:4 (n=46,43,42)	100	100	19.0	
Serogroup W: >=1:8 (n=46,43,42)	100	100	16.7	
Serogroup W: >=1:16 (n=46,43,42)	100	100	16.7	
Serogroup W: >=1:32 (n=46,43,42)	100	100	16.7	
Serogroup W: >=1:64 (n=46,43,42)	100	100	16.7	
Serogroup W: >=1:128 (n=46,43,42)	100	97.7	11.9	
Serogroup W: >=1:256 (n=46,43,42)	100	97.7	4.8	
Serogroup W: >=1:512 (n=46,43,42)	97.8	95.3	2.4	
Serogroup W: >=1:1024 (n=46,43,42)	87.0	86.0	0	
Serogroup W: >=1:2048 (n=46,43,42)	73.9	74.4	0	
Serogroup W: >=1:4096 (n=46,43,42)	39.1	46.5	0	
Serogroup W: >=1:8192 (n=46,43,0)	28.3	25.6	99999	
Serogroup W: >=1:16384 (n=46,43,0)	2.2	9.3	99999	
Serogroup W: >=1:32768 (n=46,43,0)	0	0	99999	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W: Group 1 and 2 - PPAS2

End point title	Geometric Mean Titers of Antibodies Measured by hSBA Against Meningococcal Serogroups A, C, Y, and W: Group 1 and 2 - PPAS2[35]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by hSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on per-protocol analysis set 2 (PPAS2) defined for accessing ACYW immune response data for subjects who received at least 1 dose of study vaccine in infancy and had valid post-vaccination serology results at 12 to13 months of age, with no relevant protocol violations. Here, 'n' = subjects with available data for each specified category and "vacc." = vaccination. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months) and before vaccination at the age of 12-13 months

Notes:

[35] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	36		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A: 30 days after 3-month vacc. (n=27,28)	12.7 (8.68 to 18.6)	9.28 (6.29 to 13.7)		
Serogroup A: Before 12-13 months vacc. (n=36,36)	46.1 (28.9 to 73.6)	31.4 (18.9 to 52.1)		
Serogroup C: 30 days after 3-month vacc. (n=28,28)	95.1 (54.1 to 167)	59.4 (31.6 to 112)		
Serogroup C: Before 12-13 months vacc. (n=41,36)	24.4 (15.5 to 38.5)	16.6 (9.71 to 28.5)		
Serogroup Y: 30 days after 3-month vacc. (n=29,26)	9.69 (5.69 to 16.5)	4.95 (3.39 to 7.22)		
Serogroup Y: Before 12-13 months vacc. (n=38,33)	21.4 (14.6 to 31.5)	12.4 (8.36 to 18.5)		
Serogroup W: 30 days after 3-month vacc. (n=27,28)	4.32 (2.99 to 6.24)	3.62 (2.60 to 5.05)		
Serogroup W: Before 12-13 months vacc. (n=41,35)	29.4 (18.7 to 46.3)	11.2 (7.59 to 16.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W - PPAS2

End point title	Percentage of Subjects With hSBA Antibody Titers >=1:4 and >=1:8 Against Meningococcal Serogroups A, C, Y, and W - PPAS2[36]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Percentage of subjects with hSBA antibody titers >=1.4 and >=1:8 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS2. Here, 'n' = subjects with available data for each specified category, 'vacc.' = vaccination, 'Sero' = serogroup and 'M' = month. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months) and before vaccination at the age of 12-13 months

Notes:

[36] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	36		
Units: percentage of subjects				
number (confidence interval 95%)				
Sero A: 30 days after 3M vacc.: >=1:4 (n=27,28)	88.9 (70.8 to 97.6)	89.3 (71.8 to 97.7)		
Sero A: 30 days after 3M vacc.: >=1:8 (n=27,28)	81.5 (61.9 to 93.7)	64.3 (44.1 to 81.4)		
Sero A: Before 12-13M vacc.: >=1:4 (n=36,36)	97.2 (85.5 to 99.9)	97.2 (85.5 to 99.9)		
Sero A: Before 12-13M vacc.: >=1:8 (n=36,36)	91.7 (77.5 to 98.2)	83.3 (67.2 to 93.6)		
Sero C: 30 days after 3M vacc.: >=1:4 (n=28,28)	100 (87.7 to 100)	96.4 (81.7 to 99.9)		
Sero C: 30 days after 3M vacc.: >=1:8 (n=28,28)	92.9 (76.5 to 99.1)	92.9 (76.5 to 99.1)		
Sero C: Before 12-13M vacc.: >=1:4 (n=41,36)	87.8 (73.8 to 95.9)	80.6 (64.0 to 91.8)		
Sero C: Before 12-13M vacc.: >=1:8 (n=41,36)	80.5 (65.1 to 91.2)	69.4 (51.9 to 83.7)		
Sero Y: 30 days after 3M vacc.: >=1:4 (n=29,26)	75.9 (56.5 to 89.7)	57.7 (36.9 to 76.6)		
Sero Y: 30 days after 3M vacc.: >=1:8 (n=29,26)	65.5 (45.7 to 82.1)	46.2 (26.6 to 66.6)		
Sero Y: Before 12-13M vacc.: >=1:4 (n=38,33)	94.7 (82.3 to 99.4)	90.9 (75.7 to 98.1)		
Serogroup Y: Before 12-13M vacc.: >=1:8 (n=38,33)	89.5 (75.2 to 97.1)	78.8 (61.1 to 91.0)		
Sero W: 30 days after 3M vacc.: >=1:4 (n=27,28)	51.9 (31.9 to 71.3)	39.3 (21.5 to 59.4)		
Sero W: 30 days after 3M vacc.: >=1:8 (n=27,28)	37.0 (19.4 to 57.6)	28.6 (13.2 to 48.7)		
Sero W: Before 12-13M vacc.: >=1:4 (n=41,35)	92.7 (80.1 to 98.5)	88.6 (73.3 to 96.8)		

Sero W: Before 12-13M vacc.: >=1:8 (n=41,35)	85.4 (70.8 to 94.4)	68.6 (50.7 to 83.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W: Group 1 and 2 - PPAS2

End point title	Geometric Mean Titers of Antibodies Measured by rSBA Against Meningococcal Serogroups A, C, Y, and W: Group 1 and 2 - PPAS2[37]

End point description:

GMTs of antibody against meningococcal serogroups A, C, Y, and W were measured by rSBA. Titers were expressed in terms of 1/dilution. Analysis was performed on PPAS2. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category and 'vacc.' = vaccination. Here, '-99999' and '99999' are used as space filler and denotes that 95% CI was not computable as the sample size was too small to compute valid data. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months) and before vaccination at the age of 12-13 months

Notes:

[37] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: titers				
geometric mean (confidence interval 95%)				
Serogroup A: 30 days after 3-month vacc. (n=3,6)	80.6 (-99999 to 99999)	18.0 (3.33 to 96.9)		
Serogroup A: Before 12-13 months vacc. (n=7,9)	21.5 (1.29 to 360)	27.4 (2.92 to 258)		
Serogroup C: 30 days after 3-month vacc. (n=4,6)	431 (-99999 to 99999)	144 (44.8 to 461)		
Serogroup C: Before 12-13 months vacc. (n=8,9)	38.1 (9.61 to 151)	11.8 (1.96 to 70.4)		
Serogroup Y: 30 days after 3-month vacc. (n=3,6)	323 (-99999 to 99999)	102 (22.6 to 456)		
Serogroup Y: Before 12-13 months vacc. (n=8,8)	69.8 (11.0 to 441)	20.7 (3.81 to 113)		
Serogroup W: 30 days after 3-month vacc. (n=4,6)	256 (-99999 to 99999)	90.5 (5.16 to 1587)		
Serogroup W: Before 12-13 months vacc. (n=6,9)	16.0 (1.40 to 183)	4.67 (1.80 to 12.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W - PPAS2

End point title	Percentage of Subjects With rSBA Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W - PPAS2[38]

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by rSBA assay. Percentage of subjects with rSBA antibody titers >=1:8 and >=1:128 for meningococcal serogroups A, C, Y, and W were reported in this endpoint. Analysis was performed on PPAS2. Here, 'number of subjects analysed' = subjects with available data for this endpoint and 'n' = subjects with available data for each specified category, 'Sero' = serogroup, 'M' = months and 'vacc.' = vaccination. Data for this endpoint was not planned to be collected and analysed for Group 3.

End point type	Secondary

End point timeframe:

30 days post-vaccination at the age of 3 months (i.e., at the age of 4 months) and before vaccination at the age of 12-13 months

Notes:

[38] - 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: Endpoint is reporting data for applicable arms in the study.

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: percentage of subjects				
number (confidence interval 95%)				
Sero A: 30 days after 3M vacc.: >=1:8 (n=3,6)	66.7 (9.4 to 99.2)	66.7 (22.3 to 95.7)		
Sero A: 30 days after 3M vacc.: >=1:128 (n=3,6)	66.7 (9.4 to 99.2)	16.7 (0.4 to 64.1)		
Sero A: Before 12-13M vacc.: >=1:8 (n=7,9)	42.9 (9.9 to 81.6)	55.6 (21.2 to 86.3)		
Sero A: Before 12-13M vacc.: >=1:128 (n=7,9)	42.9 (9.9 to 81.6)	44.4 (13.7 to 78.8)		
Sero C: 30 days after 3M vacc.: >=1:8 (n=4,6)	100 (39.8 to 100)	100 (54.1 to 100)		
Sero C: 30 days after 3M vacc.: >=1:128 (n=4,6)	100 (39.8 to 100)	83.3 (35.9 to 99.6)		
Sero C: Before 12-13M vacc.: >=1:8 (n=8,9)	87.5 (47.3 to 99.7)	55.6 (21.2 to 86.3)		
Sero C: Before 12-13M vacc.: >=1:128 (n=8,9)	37.5 (8.5 to 75.5)	11.1 (0.3 to 48.2)		

Sero Y: 30 days after 3M vacc.: >=1:8 (n=3,6)	100 (29.2 to 100)	100 (54.1 to 100)		
Sero Y: 30 days after 3M vacc.: >=1:128 (n=3,6)	100 (29.2 to 100)	50.0 (11.8 to 88.2)		
Sero Y: Before 12-13M vacc.: >=1:8 (n=8,8)	87.5 (47.3 to 99.7)	62.5 (24.5 to 91.5)		
Serogroup Y: Before 12-13M vacc.: >=1:128 (n=8,8)	37.5 (8.5 to 75.5)	25.0 (3.2 to 65.1)		
Sero W: 30 days after 3M vacc.: >=1:8 (n=4,6)	100 (39.8 to 100)	66.7 (22.3 to 95.7)		
Sero W: 30 days after 3M vacc.: >=1:128 (n=4,6)	100 (39.8 to 100)	66.7 (22.3 to 95.7)		
Sero W: Before 12-13M vacc.: >=1:8 (n=6,9)	50.0 (11.8 to 88.2)	33.3 (7.5 to 70.1)		
Sero W: Before 12-13M vacc.: >=1:128 (n=6,9)	33.3 (4.3 to 77.7)	0 (0 to 33.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Injection Site Reactions After Any Vaccination

End point title	Number of Subjects With Solicited Injection Site Reactions After Any Vaccination

End point description:

Solicited reaction (SR) was defined as "expected" adverse reaction (AR) (sign or symptom) observed and reported under conditions (nature and onset) pre-listed (i.e., solicited) in protocol and case report form (CRF) and considered as related to vaccination. Solicited injection site reactions included injection site tenderness, injection site erythema, and injection site swelling and were planned to be collected and reported for each vaccine separately; and not planned to be collected for Rotavirus vaccine as vaccine was administered orally, and no injection site reactions were expected to occur. Reported AEs for each arm were presented as pre-specified in study protocol. Analysed on safety analysis set that included all subjects who had received at least 1 dose of study vaccines and had any safety data available. '99999' is used as space filler for MenACYW categories and signifies that no subject was evaluable because in Group 3 MenACYW vaccine was not administered.

End point type	Secondary

End point timeframe:

Within 7 days post any vaccination

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	314[39]	314[40]	157[41]	
Units: subjects				
MenACYW conjugate: Tenderness (n=309,309,0)	198	161	99999	
MenACYW conjugate: Erythema (n=309,309,0)	220	205	99999	
MenACYW conjugate: Swelling (n=309,309,0)	139	111	99999	

Bexsero: Tenderness (n=310,312,155)	266	230	138	
Bexsero: Erythema (n=310,312,155)	271	246	136	
Bexsero: Swelling (n=310,312,155)	234	192	118	
Infanrix hexa: Tenderness (n=309,312,155)	220	216	119	
Infanrix hexa: Erythema (n=309,312,155)	254	231	117	
Infanrix hexa: Swelling (n=309,312,155)	188	189	86	
Prevnar 13: Tenderness (n=309,312,155)	195	196	118	
Prevnar 13: Erythema (n=309,311,155)	214	202	104	
Prevnar 13: Swelling (n=309,311,155)	140	137	69	

Notes:

[39] - 'n' = subjects with available data for each specified category.

[40] - 'n' = subjects with available data for each specified category.

[41] - 'n' = subjects with available data for each specified category.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Systemic Reactions After Any Vaccination

End point title	Number of Subjects With Solicited Systemic Reactions After Any Vaccination

End point description:

A SR was an expected AR (sign or symptom) observed and reported under the conditions (nature and onset) prelisted (i.e., solicited) in the CRB and considered as related to the product administered. Solicited systemic reactions included fever, vomiting, crying abnormal, drowsiness, appetite lost, and irritability. 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.

End point type	Secondary

End point timeframe:

Within 7 days after any vaccination

End point values	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	314	314	157	
Units: subjects				
Fever (n=309,312,155)	100	86	50	
Vomiting (n=310,312,155)	173	172	71	
Crying abnormal (n=310,312,155)	293	273	141	
Appetite lost (n=310,312,155)	230	230	121	
Drowsiness (n=310,312,155)	275	275	137	
Irritability (n=310,312,155)	306	299	147	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited AEs: before first vacc. at age of 3 months up to 30 days post any vacc. SRs: within 7 days post any vacc. Serious AEs: before first vacc. at age of 3 months up to 30 days post last vaccination in each group (i.e., up to age of 13 to 14 months)

Adverse event reporting additional description:

SR: "expected" AR observed & reported under conditions pre-listed in protocol and CRF. Safety set. Reported AEs for each arm were presented as pre-specified in protocol. In AE section, SR: Fever, Crying abnormal, Drowsiness, and Appetite lost are reported under Pyrexia, Crying, Somnolence, & decreased appetite, respectively.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine + Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Reporting group title	Group 3: Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received Bexsero® vaccine at 2, 4, and 12 to 13 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Reporting group title	Group 2: MenACYW Conjugate Vaccine + Bexsero®

Reporting group description:

Subjects aged 2 months (at the time of enrollment) received MenACYW Conjugate vaccine at 3 months and at 12 to 13 months of age, Bexsero® vaccine at 2 and 4 months of age along with Infanrix hexa® vaccine at 2, 3, and 4 months of age; Rotarix® vaccine at 2 and 3 months of age; and Prevenar 13® vaccine at 2 and 4 months of age.

Serious adverse events	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 314 (5.73%)	7 / 157 (4.46%)	34 / 314 (10.83%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Head Injury			
subjects affected / exposed	0 / 314 (0.00%)	1 / 157 (0.64%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic			

disorders			
Cystic Lymphangioma			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Vascular disorders			
Cyanosis			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Seizure			
subjects affected / exposed	2 / 314 (0.64%)	1 / 157 (0.64%)	0 / 314 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head Titubation			
subjects affected / exposed	0 / 314 (0.00%)	1 / 157 (0.64%)	0 / 314 (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
Embolic Stroke			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Febrile Convulsion			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Diarrhoea			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Haematemesis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash Erythematous			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Petechiae			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Herpes Virus Infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Respiratory Tract Infection			
subjects affected / exposed	1 / 314 (0.32%)	1 / 157 (0.64%)	3 / 314 (0.96%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph Node Abscess			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
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 Viral			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Bronchiolitis			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastroenteritis			
subjects affected / exposed	2 / 314 (0.64%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Bronchiolitis			
subjects affected / exposed	3 / 314 (0.96%)	3 / 157 (1.91%)	4 / 314 (1.27%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Sepsis			
subjects affected / exposed	2 / 314 (0.64%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Rash			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection Viral			

subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	0 / 314 (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
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
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			
Weight Gain Poor			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	1 / 314 (0.32%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure To Thrive			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	2 / 314 (0.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 314 (0.00%)	0 / 157 (0.00%)	1 / 314 (0.32%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Group 1: MenACYW Conjugate Vaccine + Bexsero®	Group 3: Bexsero®	Group 2: MenACYW Conjugate Vaccine + Bexsero®
Total subjects affected by non-serious adverse events			
subjects affected / exposed	310 / 314 (98.73%)	155 / 157 (98.73%)	310 / 314 (98.73%)
Nervous system disorders			
Somnolence			

subjects affected / exposed	275 / 314 (87.58%)	137 / 157 (87.26%)	275 / 314 (87.58%)
occurrences (all)	688	320	636
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	115 / 314 (36.62%)	58 / 157 (36.94%)	105 / 314 (33.44%)
occurrences (all)	157	77	137
Injection Site Swelling			
subjects affected / exposed	262 / 314 (83.44%)	127 / 157 (80.89%)	248 / 314 (78.98%)
occurrences (all)	1161	466	909
Injection Site Pain			
subjects affected / exposed	277 / 314 (88.22%)	141 / 157 (89.81%)	263 / 314 (83.76%)
occurrences (all)	1521	745	1295
Injection Site Erythema			
subjects affected / exposed	294 / 314 (93.63%)	144 / 157 (91.72%)	281 / 314 (89.49%)
occurrences (all)	1806	685	1455
Injection Site Bruising			
subjects affected / exposed	92 / 314 (29.30%)	35 / 157 (22.29%)	89 / 314 (28.34%)
occurrences (all)	154	64	137
Crying			
subjects affected / exposed	294 / 314 (93.63%)	141 / 157 (89.81%)	274 / 314 (87.26%)
occurrences (all)	820	418	709
Injection Site Mass			
subjects affected / exposed	26 / 314 (8.28%)	14 / 157 (8.92%)	22 / 314 (7.01%)
occurrences (all)	46	24	40
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	12 / 314 (3.82%)	8 / 157 (5.10%)	16 / 314 (5.10%)
occurrences (all)	13	8	16
Vomiting			
subjects affected / exposed	177 / 314 (56.37%)	72 / 157 (45.86%)	174 / 314 (55.41%)
occurrences (all)	323	144	291
Teething			
subjects affected / exposed	112 / 314 (35.67%)	62 / 157 (39.49%)	115 / 314 (36.62%)
occurrences (all)	195	98	184
Gastrooesophageal Reflux Disease			

subjects affected / exposed	18 / 314 (5.73%)	7 / 157 (4.46%)	14 / 314 (4.46%)
occurrences (all)	19	8	16
Diarrhoea			
subjects affected / exposed	42 / 314 (13.38%)	23 / 157 (14.65%)	32 / 314 (10.19%)
occurrences (all)	46	26	42
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	30 / 314 (9.55%)	9 / 157 (5.73%)	37 / 314 (11.78%)
occurrences (all)	35	11	43
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	20 / 314 (6.37%)	9 / 157 (5.73%)	30 / 314 (9.55%)
occurrences (all)	23	9	33
Eczema			
subjects affected / exposed	10 / 314 (3.18%)	9 / 157 (5.73%)	12 / 314 (3.82%)
occurrences (all)	10	9	14
Psychiatric disorders			
Irritability			
subjects affected / exposed	306 / 314 (97.45%)	147 / 157 (93.63%)	299 / 314 (95.22%)
occurrences (all)	999	472	905
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	66 / 314 (21.02%)	29 / 157 (18.47%)	56 / 314 (17.83%)
occurrences (all)	98	39	75
Conjunctivitis			
subjects affected / exposed	16 / 314 (5.10%)	2 / 157 (1.27%)	11 / 314 (3.50%)
occurrences (all)	16	2	11
Upper Respiratory Tract Infection			
subjects affected / exposed	35 / 314 (11.15%)	11 / 157 (7.01%)	37 / 314 (11.78%)
occurrences (all)	40	15	51
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	18 / 314 (5.73%)	4 / 157 (2.55%)	19 / 314 (6.05%)
occurrences (all)	20	5	22
Metabolism and nutrition disorders			
Decreased Appetite			

subjects affected / exposed occurrences (all)	230 / 314 (73.25%) 443	121 / 157 (77.07%) 239	230 / 314 (73.25%) 425

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 June 2019	Following changes were made: Team member updated on cover page; Updated version number and date on the cover page; Blood sample collection time points were amended such that about half of the subjects who had blood collected at Visit 2 had the blood collection at Visit 4 before vaccination to allow for the evaluation of the immune response persistence after one dose of MenACYW Conjugate vaccine given at 3 months of age and prior to the dose given in the second year of life; Synopsis updated to include persistence assessment in immunogenicity observational objective; Modified synopsis to include collection of maternal prenatal immunization against pertussis; Clarified the blood collection at Visit 2, 3 and 4; Clarified that the diary card dispensed at each visit is based on the number of vaccines received at that visit; Background of the Investigational Product modified to update the number of individuals that had received MenACYW Conjugate vaccine in clinical trials to date; Modified justification of study design to include the blood draw at Visit 4 and the evaluation of persistence and the effect of the 2nd dose of MenACYW Conjugate vaccine; Modified study plan table to clarify the blood collection at every visit per subset A and B; References added to the licensed products package inserts; Modified safety definition: "By definition, solicited reactions are to be considered as being related to the product administered"; Modified safety analysis sets to include the persistence and the effect of 2nd dose of MenACYW Conjugate vaccine; Modified per-protocol analysis set to clarify the immunogenicity analysis (the definition of per protocol analysis set for each analysis point) and add the persistence analysis; Modified confidentiality of data, data protection and access to subject record section to align with the most recent protocol template and the GDPR.
03 May 2021	Following changes were made: Updated cover page to reflect Resident Medical officer and global safety officer responsible for the study; Updated version number and date; Updated the history of protocol versions table to reflect all the protocol amendments; Updated the study period; Updated synopsis - study design, schedule of study procedures and methodology as during the study conduct, rather high attrition rate was noted especially during the COVID-19 pandemic year of 2020 which led the study team to increase the sample size for maintaining an acceptable overall power of primary hypothesis. Main factors of attrition had been the visits outside of time windows, no blood draws performed at some visits and routine pediatric vaccine administration outside of the time window. No safety concerns were identified; Added clarification to the primary objective; One immunogenicity endpoint initially listed as an Observational objective was placed under Secondary objectives. The language was slightly modified to improve clarity; Updated justification of the study design to clarify that the study also aimed to evaluate immune persistence following the dose in infancy; Minor changes to improve the clarity in the concomitant medication and other therapies section; Updated sample storage and shipment section to align with the new department name; A new section on the sensitivity analysis was added to document the impact of coronavirus disease 2019 (COVID-19) pandemic situation on the study conduct; Revised text to clarify how the group classification was done for subjects who did not complete the study; Updated safety analysis set to clarify safety data after vaccination at 4 months of age would be summarized based on MenACYW Conjugate vaccination at 3 months of age and routine vaccine injection at 4 months of age; Harmonised text in per-protocol set for immunogenicity evaluation after infant vaccination to align with concomitant medications and therapies section.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported