# 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<br>Units: Subjects | | | |
| Age continuous<br>Units: days | | | |
| arithmetic mean | 64.7 | 63.9 | 64.8 |
| standard deviation | ± 6.88 | ± 6.73 | ± 7.03 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 148 | 154 | 81 |
| Male | 166 | 161 | 77 |
| Missing | 0 | 1 | 0 |
| Race (NIH/OMB)<br>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<br>Units: Subjects | | | |

| | | | |
|---|---|---|---|
| Age continuous<br>Units: days<br>arithmetic mean<br>standard deviation | -<br>- | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 383 | | |
| Male | 404 | | |
| Missing | 1 | | |
| Race (NIH/OMB)<br>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<br>occurrences (all) | 230 / 314 (73.25%)<br>443 | 121 / 157 (77.07%)<br>239 | 230 / 314 (73.25%)<br>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