



Clinical trial results:

A Phase 3b, Open-Label, Study to Evaluate the Safety and Immunogenicity of Nimenrix® in Healthy Infants, Given at 3 and 12 Months of Age

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2020-005059-19 |
| Trial protocol | FI PL |
| Global end of trial date | 09 September 2022 |

Results information

| | |
|--------------------------------|-------------------|
| Result version number | v2 (current) |
| This version publication date | 23 September 2023 |
| First version publication date | 05 March 2023 |
| Version creation reason | |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | C0921062 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04819113 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 10 January 2023 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 September 2022 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Safety: To describe the safety of 2 doses of Nimenrix when administered in healthy infants at 3 and 12 months of age.

Immunogenicity: To describe the immune response for *Neisseria meningitidis* serogroups A, C, W-135, and Y induced by 2 doses of Nimenrix administered at 3 and 12 months of age.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 09 April 2021 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Finland: 95 |
| Country: Number of subjects enrolled | Poland: 26 |
| Country: Number of subjects enrolled | Spain: 24 |
| Worldwide total number of subjects | 145 |
| EEA total number of subjects | 145 |

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) | 145 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |

| | |
|---------------------|---|
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 153 subjects were screened, of which 4 were screen failures. 149 subjects were enrolled and randomised in study of which 2 subjects did not receive any vaccination. 147 subjects received vaccination of which 2 subjects received at least 1 dose of vaccination but had no available safety information; hence, excluded from safety population.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|----------|
| Arm title | Nimenrix |
|-----------|----------|

Arm description:

Subjects aged 3 months were administered a single dose of 0.5 milliliter (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1 (Visit 1) and a second dose of Nimenrix (Vaccination 2) at 12 months of age (Visit 3). Subjects had a safety follow-up visit 1 month after each vaccination (Visit 2 and Visit 4 respectively).

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solvent for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 0.5 mL of Nimenrix intramuscularly into the left thigh muscle at Visits 1 and 3.

| Number of subjects in period 1 | Nimenrix |
|--------------------------------|----------|
| Started | 145 |
| Completed | 141 |
| Not completed | 4 |
| Lost to follow-up | 1 |
| Withdrawal by parent/guardian | 3 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Nimenrix |
|-----------------------|----------|

Reporting group description:

Subjects aged 3 months were administered a single dose of 0.5 milliliter (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1 (Visit 1) and a second dose of Nimenrix (Vaccination 2) at 12 months of age (Visit 3). Subjects had a safety follow-up visit 1 month after each vaccination (Visit 2 and Visit 4 respectively).

| Reporting group values | Nimenrix | Total | |
|--|----------|-------|--|
| Number of subjects | 145 | 145 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 145 | 145 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age Continuous | | | |
| Units: Days | | | |
| arithmetic mean | 94.4 | | |
| standard deviation | ± 6.09 | - | |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | 76 | 76 | |
| Male | 69 | 69 | |
| Race | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 1 | 1 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 0 | 0 | |
| White | 141 | 141 | |
| More than one race | 2 | 2 | |
| Unknown or Not Reported | 1 | 1 | |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 26 | 26 | |
| Not Hispanic or Latino | 119 | 119 | |
| Unknown or Not Reported | 0 | 0 | |

End points

End points reporting groups

| | |
|--|----------|
| Reporting group title | Nimenrix |
| Reporting group description: Subjects aged 3 months were administered a single dose of 0.5 milliliter (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1 (Visit 1) and a second dose of Nimenrix (Vaccination 2) at 12 months of age (Visit 3). Subjects had a safety follow-up visit 1 month after each vaccination (Visit 2 and Visit 4 respectively). | |

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2

| | |
|--|--|
| End point title | Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2 ^[1] |
| End point description: Local reactions included pain at injection site, redness and swelling and were recorded by the subject's parents/legal guardians in an electronic diary (e-diary). Redness and swelling were measured and recorded in measuring device units. 1 measuring device unit = 0.5 centimeter (cm) and graded as mild: greater than (>) 0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; and severe: >7.0 cm. Pain at injection site was graded as mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: limited limb movement. Exact 2-sided confidence interval (CI) was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, "Number of Subjects Analysed (N)" signifies subjects evaluable for this endpoint. | |
| End point type | Primary |
| End point timeframe: Within 7 days after vaccination 2 | |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|-----------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 142 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Pain at injection site: Mild | 19.7 (13.5 to 27.2) | | | |
| Pain at injection site: Moderate | 7.7 (3.9 to 13.4) | | | |
| Pain at injection site: Severe | 0 (0.0 to 2.6) | | | |
| Redness: Mild | 14.1 (8.8 to 20.9) | | | |
| Redness: Moderate | 2.8 (0.8 to 7.1) | | | |
| Redness: Severe | 0 (0.0 to 2.6) | | | |
| Swelling: Mild | 4.9 (2.0 to 9.9) | | | |
| Swelling: Moderate | 1.4 (0.2 to 5.0) | | | |
| Swelling: Severe | 0 (0.0 to 2.6) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2

| | |
|-----------------|--|
| End point title | Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2 ^[2] |
|-----------------|--|

End point description:

Systemic event: fever, decreased appetite, increased sleep, irritability were recorded by subject's parents/legal guardian in e-diary. Fever: temperature greater than or equal to (\geq) 38.0 degrees (deg) Celsius (C), categorised: ≥ 38.0 to 38.4 deg C, > 38.4 to 38.9 deg C, > 38.9 to 40.0 deg C; > 40.0 deg C; decreased appetite graded as mild: decreased interest in eating, moderate: decreased oral intake; severe: refusal to feed; increased sleep graded as mild: increased/prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity; severe: disabling, not interested in usual daily activity; irritability graded as mild: easily consolable, moderate: required increased attention; severe: inconsolable, crying could not be comforted. Exact 2-sided CI was based on Clopper & Pearson method. Dose 2 safety population: subjects who received investigational product at Visit(V) 1 and 3 and safety information was available from V3. Here, N= subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 7 days after vaccination 2

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 142 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: ≥ 38.0 deg C to 38.4 deg C | 6.3 (2.9 to 11.7) | | | |
| Fever: > 38.4 deg C to 38.9 deg C | 4.9 (2.0 to 9.9) | | | |
| Fever: > 38.9 deg C to 40.0 deg C | 3.5 (1.2 to 8.0) | | | |
| Fever: > 40.0 deg C | 0 (0.0 to 2.6) | | | |
| Decreased appetite: Mild | 19.7 (13.5 to 27.2) | | | |
| Decreased appetite: Moderate | 11.3 (6.6 to 17.7) | | | |
| Decreased appetite: Severe | 1.4 (0.2 to 5.0) | | | |
| Increased sleep: Mild | 38.0 (30.0 to 46.5) | | | |
| Increased sleep: Moderate | 11.3 (6.6 to 17.7) | | | |
| Increased sleep: Severe | 1.4 (0.2 to 5.0) | | | |
| Irritability: Mild | 18.3 (12.3 to 25.7) | | | |
| Irritability: Moderate | 42.3 (34.0 to 50.8) | | | |
| Irritability: Severe | 2.8 (0.8 to 7.1) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 2

| | |
|-----------------|--|
| End point title | Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 2 ^[3] |
|-----------------|--|

End point description:

The use of antipyretic medication was recorded by the subject's parents/legal guardians in an e-diary for 7 days after vaccination. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 7 days after vaccination 2

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|-----------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 142 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 55.6 (47.1 to 64.0) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) Within 30 Days After Vaccination 2

| | |
|-----------------|--|
| End point title | Percentage of Subjects With Adverse Events (AEs) Within 30 Days After Vaccination 2 ^[4] |
|-----------------|--|

End point description:

An AE was any untoward medical occurrence in a participant, temporally associated with the use of investigational product, whether or not considered related to the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e., excluding local reactions and systemic events) were reported in this endpoint. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 30 days after vaccination 2

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|-----------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 143 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 19.6 (13.4 to 27.0) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Serious Adverse Events (SAEs) Within 30 Days After Vaccination 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Serious Adverse Events (SAEs) Within 30 Days After Vaccination 2 ^[5] |
|-----------------|---|

End point description:

An SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalization or prolongation of existing hospitalization; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 30 days after vaccination 2

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|-----------------------------------|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 143 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 1.4 (0.2 to 5.0) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Newly Diagnosed Chronic Medical Conditions (NDCMCs) Within 30 Days After Vaccination 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Newly Diagnosed Chronic Medical Conditions (NDCMCs) Within 30 Days After Vaccination 2 ^[6] |
|-----------------|---|

End point description:

An NDCMC was defined as a significant disease or medical condition, not previously identified, that was expected to be persistent or was otherwise long-lasting in its effects. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was

available from Visit 3. Here, " Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 30 days after vaccination 2

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| | | | | |
|----------------------------------|------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 143 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0.0 (0.0 to 2.5) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 2 ^[7] |
|-----------------|---|

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after administration of the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, " Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Within 30 minutes after vaccination 2

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| | | | | |
|----------------------------------|------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 143 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0.0 (0.0 to 2.5) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving Serum Bactericidal Assay Using Rabbit

Complement (rSBA) Titers $\geq 1:8$ for Each Serogroup, Neisseria Meningitidis Group (Men) A, MenC, MenW-135 and MenY at Baseline: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titers $\geq 1:8$ for Each Serogroup, Neisseria Meningitidis Group (Men) A, MenC, MenW-135 and MenY at Baseline: Post Dose 2 Evaluable Immunogenicity Population ^[8] |
|-----------------|--|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline in subjects who received vaccinations 1 and 2 were reported in this endpoint. Exact 2-sided confidence interval (CI) using the Clopper and Pearson method was presented. Analysis was performed on Post Dose (PD) 2 Evaluable Immunogenicity Population (EIP) (PD2 EIP). PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N = subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At baseline (before vaccination 1)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|----------------------------------|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 128 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA | 0.0 (0.0 to 2.8) | | | |
| MenC | 4.7 (1.7 to 9.9) | | | |
| MenW-135 | 0.8 (0.0 to 4.3) | | | |
| MenY | 7.8 (3.8 to 13.9) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After vaccination 1: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After vaccination 1: Post Dose 2 Evaluable Immunogenicity Population ^[9] |
|-----------------|---|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at 1 month after vaccination 1 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N

=subjects evaluable for this endpoint.

| | |
|---|---------|
| End point type | Primary |
| End point timeframe: | |
| 1 month after vaccination 1 | |
| Notes: | |
| [9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. | |
| Justification: No statistical analysis was planned for this endpoint | |

| | | | | |
|----------------------------------|---------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA | 82.3 (74.4 to 88.5) | | | |
| MenC | 91.1 (84.7 to 95.5) | | | |
| MenW-135 | 89.5 (82.7 to 94.3) | | | |
| MenY | 90.3 (83.7 to 94.9) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY before Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY before Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population ^[10] |
|-----------------|--|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY before vaccination 2 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N =subjects evaluable for this endpoint.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| Before vaccination 2 | |
| Notes: | |
| [10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. | |
| Justification: No statistical analysis was planned for this endpoint | |

| End point values | Nimenrix | | | |
|----------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 125 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA | 33.6 (25.4 to 42.6) | | | |
| MenC | 64.8 (55.8 to 73.1) | | | |
| MenW-135 | 67.2 (58.2 to 75.3) | | | |
| MenY | 66.4 (57.4 to 74.6) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population ^[11] |
|-----------------|--|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at 1 month after vaccination 2 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N =subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

1 month after vaccination 2

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|----------------------------------|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 128 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA | 100.0 (97.2 to 100.0) | | | |
| MenC | 100.0 (97.2 to 100.0) | | | |
| MenW-135 | 100.0 (97.2 to 100.0) | | | |
| MenY | 100.0 (97.2 to 100.0) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Geometric Mean Titers (GMTs) of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline: Post Dose 2 Evaluable Immunogenicity Population ^[12] |
|-----------------|--|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the rSBA titers (based on the Student t distribution). PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N =subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At baseline (before vaccination 1)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|--|------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 128 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA | 4.0 (4.0 to 4.0) | | | |
| MenC | 4.4 (4.0 to 4.7) | | | |
| MenW-135 | 4.1 (3.9 to 4.3) | | | |
| MenY | 5.0 (4.3 to 5.8) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 1: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and |
|-----------------|---|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the rSBA titers (based on the Student t distribution). PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N =subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

1 month after vaccination 1

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|--|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 124 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA | 54.7 (41.1 to 72.9) | | | |
| MenC | 107.6 (81.3 to 142.5) | | | |
| MenW-135 | 202.4 (149.6 to 274.0) | | | |
| MenY | 187.2 (141.6 to 247.5) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups before Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups before Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population ^[14] |
|-----------------|---|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the rSBA titers (based on the Student t distribution). Dose 2 safety population included subjects who received the first and second dose of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3. Here, "Overall Number of Subjects Analyzed" signifies subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Before vaccination 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 125 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA | 9.9 (7.6 to 13.0) | | | |
| MenC | 21.8 (16.1 to 29.5) | | | |
| MenW-135 | 21.7 (16.3 to 28.9) | | | |
| MenY | 24.5 (18.0 to 33.4) | | | |

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population ^[15] |
|-----------------|---|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the rSBA titers (based on the Student t distribution). PD2 EIP: subjects enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and at 1 month after dose 2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, N =subjects evaluable for this endpoint.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

1 month after vaccination 2

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No statistical analysis was planned for this endpoint

| End point values | Nimenrix | | | |
|--|-----------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 128 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|----------|---------------------------|--|--|--|
| MenA | 1818.0 (1497.8 to 2206.6) | | | |
| MenC | 1299.5 (1052.3 to 1604.9) | | | |
| MenW-135 | 2714.1 (2233.0 to 3298.8) | | | |
| MenY | 1667.1 (1393.9 to 1993.8) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1 |
|-----------------|---|

End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by the subject's parents/legal guardians in an e-diary. Redness and swelling were measured and recorded in measuring device units. 1 measuring device unit = 0.5 cm and graded as mild: >0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; and severe: >7.0 cm. Pain at injection site was graded as mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: limited limb movement. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 7 days after vaccination 1

| End point values | Nimenrix | | | |
|----------------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Pain at injection site: Mild | 13.8 (8.6 to 20.5) | | | |
| Pain at injection site: Moderate | 2.8 (0.8 to 6.9) | | | |
| Pain at injection site: Severe | 0 (0.0 to 2.5) | | | |
| Redness: Mild | 6.2 (2.9 to 11.5) | | | |
| Redness: Moderate | 1.4 (0.2 to 4.9) | | | |
| Redness: Severe | 0 (0.0 to 2.5) | | | |
| Swelling: Mild | 1.4 (0.2 to 4.9) | | | |
| Swelling: Moderate | 1.4 (0.2 to 4.9) | | | |
| Swelling: Severe | 0 (0.0 to 2.5) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1

| | |
|--|---|
| End point title | Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1 |
| End point description: | |
| Systemic events included fever, decreased appetite, increased sleep and irritability and were recorded in e-diary. Fever was defined as temperature ≥ 38.0 deg C, categorized as ≥ 38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C; decreased appetite graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed; increased sleep graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity; irritability graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Exact 2-sided CI was based on Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. | |
| End point type | Secondary |
| End point timeframe: | |
| Within 7 days after vaccination 1 | |

| End point values | Nimenrix | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Fever: ≥ 38.0 deg C to 38.4 deg C | 7.6 (3.8 to 13.2) | | | |
| Fever: >38.4 deg C to 38.9 deg C | 2.1 (0.4 to 5.9) | | | |
| Fever: >38.9 deg C to 40.0 deg C | 0 (0.0 to 2.5) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 2.5) | | | |
| Decreased appetite: Mild | 15.2 (9.8 to 22.1) | | | |
| Decreased appetite: Moderate | 8.3 (4.3 to 14.0) | | | |
| Decreased appetite: Severe | 0 (0.0 to 2.5) | | | |
| Increased sleep: Mild | 57.2 (48.8 to 65.4) | | | |
| Increased sleep: Moderate | 7.6 (3.8 to 13.2) | | | |
| Increased sleep: Severe | 1.4 (0.2 to 4.9) | | | |
| Irritability: Mild | 27.6 (20.5 to 35.6) | | | |
| Irritability: Moderate | 40.0 (32.0 to 48.5) | | | |

| | | | | |
|----------------------|------------------|--|--|--|
| Irritability: Severe | 4.8 (2.0 to 9.7) | | | |
|----------------------|------------------|--|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 1

| | |
|--|---|
| End point title | Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 1 |
| End point description: | |
| The use of antipyretic medication was recorded by the participant's parents/legal guardians in an e-diary for 7 days after vaccination. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. | |
| End point type | Secondary |
| End point timeframe: | |
| Within 7 days after vaccination 1 | |

| | | | | |
|----------------------------------|---------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 39.3 (31.3 to 47.8) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With AEs Within 30 Days After Vaccination 1

| | |
|--|--|
| End point title | Percentage of Subjects With AEs Within 30 Days After Vaccination 1 |
| End point description: | |
| An AE was any untoward medical occurrence in a participant, temporally associated with the use of investigational product, whether or not considered related to the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3. | |
| End point type | Secondary |
| End point timeframe: | |
| Within 30 days after vaccination 1 | |

| | | | | |
|----------------------------------|-------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 6.9 (3.4 to 12.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SAEs and NDCMCs: Within 30 Days After Vaccination 1, From 1 Month After Vaccination 1 to 9 Months After Vaccination 1, From Vaccination 1 to 9 Months After Vaccination 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects With SAEs and NDCMCs: Within 30 Days After Vaccination 1, From 1 Month After Vaccination 1 to 9 Months After Vaccination 1, From Vaccination 1 to 9 Months After Vaccination 1 |
|-----------------|---|

End point description:

An SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. An NDCMC was defined as a significant disease or medical condition, not previously identified, that was expected to be persistent or was otherwise long-lasting in its effects. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 30 days after vaccination (vacc.) 1, from 1 month (M) after vaccination 1 to 9 months after vaccination 1 and from vaccination 1 on Day 1 to 9 months after vaccination 1

| | | | | |
|--|-------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| SAE: Within 30 days after Vacc. 1 | 1.4 (0.2 to 4.9) | | | |
| SAE: From 1 M after Vacc. 1 to 9 M after Vacc. 1 | 4.1 (1.5 to 8.8) | | | |
| SAE: From Vacc. 1 to 9 M after Vacc. 1 | 5.5 (2.4 to 10.6) | | | |
| NDCMC: Within 30 days after Vacc. 1 | 0.0 (0.0 to 2.5) | | | |
| NDCMC: From 1 M after Vacc. 1 to 9 M after Vacc. 1 | 0.0 (0.0 to 2.5) | | | |
| NDCMC: From Vacc. 1 to 9 M after Vacc. 1 | 0.0 (0.0 to 2.5) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 1

| | |
|-----------------|--|
| End point title | Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 1 |
|-----------------|--|

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after administration of the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Within 30 minutes after vaccination 1

| | | | | |
|----------------------------------|------------------|--|--|--|
| End point values | Nimenrix | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 145 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | 0.0 (0.0 to 2.5) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving rSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|---|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. Analysis was performed on post-dose 1 (PD1) evaluable immunogenicity population (EIP). PD1 EIP: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and Month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At baseline (before vaccination 1) and 1 month after vaccination 1 | |

| End point values | Nimenrix | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 116 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1) | 0.0 (0.0 to 3.1) | | | |
| MenA, 1 Month after Vaccination 1 | 81.0 (72.7 to 87.7) | | | |
| MenC, Baseline (Before Vaccination 1) | 5.2 (1.9 to 10.9) | | | |
| MenC, 1 Month after Vaccination 1 | 89.7 (82.6 to 94.5) | | | |
| MenW-135, Baseline (Before Vaccination 1) | 0.9 (0.0 to 4.7) | | | |
| MenW-135, 1 Month after Vaccination 1 | 88.8 (81.6 to 93.9) | | | |
| MenY, Baseline (Before Vaccination 1) | 7.8 (3.6 to 14.2) | | | |
| MenY, 1 Month after Vaccination 1 | 87.9 (80.6 to 93.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers $\geq 1:128$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving rSBA Titers $\geq 1:128$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|---|

End point description:

Percentage of subjects achieving rSBA titer $\geq 1:128$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after vaccination 1 in subjects who received vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 EIP: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and Month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At baseline (before vaccination 1) and 1 month after vaccination 1 | |

| End point values | Nimenrix | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 116 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1) | 0.0 (0.0 to 3.1) | | | |
| MenA, 1 Month after Vaccination 1 | 35.3 (26.7 to 44.8) | | | |
| MenC, Baseline (Before Vaccination 1) | 0.0 (0.0 to 3.1) | | | |
| MenC, 1 Month after Vaccination 1 | 65.5 (56.1 to 74.1) | | | |
| MenW-135, Baseline (Before Vaccination 1) | 0.9 (0.0 to 4.7) | | | |
| MenW-135, 1 Month after Vaccination 1 | 79.3 (70.8 to 86.3) | | | |
| MenY, Baseline (Before Vaccination 1) | 2.6 (0.5 to 7.4) | | | |
| MenY, 1 Month after Vaccination 1 | 81.0 (72.7 to 87.7) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|--|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the rSBA titers (based on the Student t distribution). Post Dose 1 Evaluable Immunogenicity Population (PD1 EIP): subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at Month 0 (V1; before dose 1) and Month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, "Number of Subjects Analysed" signifies subjects evaluable for this endpoint.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1) and 1 month after vaccination 1

| End point values | Nimenrix | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 116 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1) | 4.0 (4.0 to 4.0) | | | |
| MenA, 1 Month after Vaccination 1 | 50.1 (37.2 to 67.5) | | | |

| | | | | |
|---|------------------------|--|--|--|
| MenC, Baseline (Before Vaccination 1) | 4.3 (4.0 to 4.5) | | | |
| MenC, 1 Month after Vaccination 1 | 96.7 (71.8 to 130.1) | | | |
| MenW-135, Baseline (Before Vaccination 1) | 4.1 (3.9 to 4.4) | | | |
| MenW-135, 1 Month after Vaccination 1 | 193.3 (140.8 to 265.5) | | | |
| MenY, Baseline (Before Vaccination 1) | 4.8 (4.2 to 5.4) | | | |
| MenY, 1 Month after Vaccination 1 | 172.6 (126.6 to 235.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titers $\geq 1:4$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titers $\geq 1:4$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|---|

End point description:

Percentage of subjects achieving hSBA titers $\geq 1:4$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 EIP: subjects enrolled & eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at Month 0 (V1; before dose1) and Month1 (V2; 1 month after dose1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviation through V2. Here, N=signifies subjects evaluable for this endpoint and n=subjects evaluable for specified rows.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1) and 1 month after vaccination 1

| End point values | Nimenrix | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 107 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=92 | 7.6 (3.1 to 15.1) | | | |
| MenA, 1 Month after Vaccination 1, n=106 | 94.3 (88.1 to 97.9) | | | |
| MenC, Baseline (Before Vaccination 1), n=100 | 13.0 (7.1 to 21.2) | | | |
| MenC, 1 Month after Vaccination 1, n=107 | 91.6 (84.6 to 96.1) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=58 | 13.8 (6.1 to 25.4) | | | |

| | | | | |
|--|---------------------|--|--|--|
| MenW-135, 1 Month after Vaccination 1, n=62 | 33.9 (22.3 to 47.0) | | | |
| MenY, Baseline (Before Vaccination 1), n=66 | 25.8 (15.8 to 38.0) | | | |
| MenY, 1 Month after Vaccination 1, n=68 | 48.5 (36.2 to 61.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving hSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|---|

End point description:

Percentage of subjects achieving hSBA titers $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 EIP: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at Month 0 (V1; before dose1) and Month1 (V2; 1 month after dose1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviation through V2. Here, N= subjects evaluable for this endpoint and n=signifies subjects evaluable for specified row.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1) and 1 month after vaccination 1

| End point values | Nimenrix | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 107 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=92 | 6.5 (2.4 to 13.7) | | | |
| MenA, 1 Month after Vaccination 1, n=106 | 94.3 (88.1 to 97.9) | | | |
| MenC, Baseline (Before Vaccination 1), n=100 | 13.0 (7.1 to 21.2) | | | |
| MenC, 1 Month after Vaccination 1, n=107 | 91.6 (84.6 to 96.1) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=58 | 13.8 (6.1 to 25.4) | | | |
| MenW-135, 1 Month after Vaccination 1, n=62 | 33.9 (22.3 to 47.0) | | | |
| MenY, Baseline (Before Vaccination 1), n=66 | 25.8 (15.8 to 38.0) | | | |
| MenY, 1 Month after Vaccination 1, n=68 | 48.5 (36.2 to 61.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population |
|-----------------|--|

End point description:

GMT was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution). PD1 EIP:subjects enrolled & eligible through V2;received vaccine at V1;blood drawn for assay testing within time frames at Month 0 (V1; before dose1) & Month1 (V2;1 month after dose1>window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 & MenY assay result at V2, received no prohibited vaccines/treatment & had no protocol deviation through V2. Here, N= subjects evaluable for this endpoint and 'n' signifies subjects evaluable for specified row.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1) and 1 month after vaccination 1

| End point values | Nimenrix | | | |
|---|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 107 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=92 | 2.4 (2.1 to 2.7) | | | |
| MenA, 1 Month after Vaccination 1, n=106 | 82.0 (63.9 to 105.0) | | | |
| MenC, Baseline (Before Vaccination 1), n=100 | 2.9 (2.4 to 3.6) | | | |
| MenC, 1 Month after Vaccination 1, n=107 | 128.4 (93.3 to 176.8) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=58 | 2.9 (2.3 to 3.7) | | | |
| MenW-135, 1 Month after Vaccination 1, n=62 | 6.9 (4.4 to 10.9) | | | |
| MenY, Baseline (Before Vaccination 1), n=66 | 6.6 (3.9 to 11.3) | | | |
| MenY, 1 Month after Vaccination 1, n=68 | 19.2 (10.2 to 36.3) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers $\geq 1:4$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving hSBA Titers $\geq 1:4$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population |
|-----------------|--|

End point description:

Percentage of subjects achieving hSBA titers $\geq 1:4$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subject enrolled and eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frame at Month0 (V1;before dose1) and at 1 month after dose2 (V4>window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccine/treatment and had no protocol deviation through V4. Here, N=subjects evaluable for endpoint and n=subjects evaluable for specified row.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1), 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2

| End point values | Nimenrix | | | |
|--|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 123 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=100 | 8.0 (3.5 to 15.2) | | | |
| MenA, 1 Month after Vaccination 1, n=111 | 95.5 (89.8 to 98.5) | | | |
| MenA, Before Vaccination 2, n=108 | 49.1 (39.3 to 58.9) | | | |
| MenA, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |
| MenC, Baseline (Before Vaccination 1), n=111 | 11.7 (6.4 to 19.2) | | | |
| MenC, 1 Month after Vaccination 1, n=116 | 93.1 (86.9 to 97.0) | | | |
| MenC, Before Vaccination 2, n=121 | 85.1 (77.5 to 90.9) | | | |
| MenC, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |

| | | | | |
|---|-----------------------|--|--|--|
| MenW-135, Baseline (Before Vaccination 1), n=65 | 12.3 (5.5 to 22.8) | | | |
| MenW-135, 1 Month after Vaccination 1, n=67 | 38.8 (27.1 to 51.5) | | | |
| MenW-135, Before Vaccination 2, n=100 | 94.0 (87.4 to 97.8) | | | |
| MenW-135, 1 Month after Vaccination 2, n=119 | 100.0 (96.9 to 100.0) | | | |
| MenY, Baseline (Before Vaccination 1), n=73 | 21.9 (13.1 to 33.1) | | | |
| MenY, 1 Month after Vaccination 1, n=72 | 50.0 (38.0 to 62.0) | | | |
| MenY, Before Vaccination 2, n=106 | 70.8 (61.1 to 79.2) | | | |
| MenY, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|--|
| End point title | Percentage of Subjects Achieving hSBA Titers $\geq 1:8$ for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population |
|-----------------|--|

End point description:

Percentage of subjects achieving hSBA titers $\geq 1:8$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subjects enrolled and eligible through 1 month after vaccination2; received vaccine at V 1 and 3; blood drawn for assay testing within time frames at Month0 (V1;before dose1) and at 1month after dose2(V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, & MenY assay result at V4, received no prohibited vaccine/treatment and had no protocol deviation through V4. Here, N=subjects evaluable for endpoint and n=subjects evaluable for specified row.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1), 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2

| End point values | Nimenrix | | | |
|--|-------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 123 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=100 | 7.0 (2.9 to 13.9) | | | |

| | | | | |
|---|-----------------------|--|--|--|
| MenA, 1 Month after Vaccination 1, n=111 | 95.5 (89.8 to 98.5) | | | |
| MenA, Before Vaccination 2, n=108 | 46.3 (36.7 to 56.2) | | | |
| MenA, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |
| MenC, Baseline (Before Vaccination 1), n=111 | 11.7 (6.4 to 19.2) | | | |
| MenC, 1 Month after Vaccination 1, n=116 | 93.1 (86.9 to 97.0) | | | |
| MenC, Before Vaccination 2, n=121 | 85.1 (77.5 to 90.9) | | | |
| MenC, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=65 | 12.3 (5.5 to 22.8) | | | |
| MenW-135, 1 Month after Vaccination 1, n=67 | 38.8 (27.1 to 51.5) | | | |
| MenW-135, Before Vaccination 2, n=100 | 94.0 (87.4 to 97.8) | | | |
| MenW-135, 1 Month after Vaccination 2, n=119 | 100.0 (96.9 to 100.0) | | | |
| MenY, Baseline (Before Vaccination 1), n=73 | 21.9 (13.1 to 33.1) | | | |
| MenY, 1 Month after Vaccination 1, n=72 | 50.0 (38.0 to 62.0) | | | |
| MenY, Before Vaccination 2, n=106 | 70.8 (61.1 to 79.2) | | | |
| MenY, 1 Month after Vaccination 2, n=123 | 100.0 (97.0 to 100.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population |
|-----------------|---|

End point description:

GMTs was derived by calculating the mean on the natural log scale based on the t-distribution, then exponentiating the results. CIs were obtained by exponentiating the limits of CIs for the mean logarithm of the hSBA titers (based on the Student t distribution). PD2 EIP: subjects enrolled & eligible through 1 month after vaccination 2; received vaccine at V1 and V3; blood drawn for assay testing within time frames at Month0 (V1; before dose 1) and at 1 month after dose2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, & MenY assay result at V4, received no prohibited vaccines/treatment & had no protocol deviation through V4. Here, N=subjects evaluable for this endpoint and n=subjects evaluable for specified row.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At baseline (before vaccination 1), 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2

| End point values | Nimenrix | | | |
|---|---------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 123 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=100 | 2.4 (2.1 to 2.7) | | | |
| MenA, 1 Month after Vaccination 1, n=111 | 86.9 (68.8 to 109.8) | | | |
| MenA, Before Vaccination 2, n=108 | 9.5 (6.8 to 13.2) | | | |
| MenA, 1 Month after Vaccination 2, n=123 | 1208.4 (976.9 to 1494.8) | | | |
| MenC, Baseline (Before Vaccination 1), n=111 | 2.9 (2.3 to 3.6) | | | |
| MenC, 1 Month after Vaccination 1, n=116 | 149.8 (111.3 to 201.6) | | | |
| MenC, Before Vaccination 2, n=121 | 74.8 (52.3 to 107.0) | | | |
| MenC, 1 Month after Vaccination 2, n=123 | 7299.6 (5362.8 to 9936.0) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=65 | 2.8 (2.2 to 3.5) | | | |
| MenW-135, 1 Month after Vaccination 1, n=67 | 8.8 (5.5 to 14.2) | | | |
| MenW-135, Before Vaccination 2, n=100 | 121.6 (90.0 to 164.2) | | | |
| MenW-135, 1 Month after Vaccination 2, n=119 | 6955.8 (5922.4 to 8169.4) | | | |
| MenY, Baseline (Before Vaccination 1), n=73 | 5.7 (3.5 to 9.5) | | | |
| MenY, 1 Month after Vaccination 1, n=72 | 19.9 (10.8 to 36.6) | | | |
| MenY, Before Vaccination 2, n=106 | 45.7 (28.8 to 72.5) | | | |
| MenY, 1 Month after Vaccination 2, n=123 | 5062.1 (4202.9 to 6097.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers \geq 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving rSBA Titers \geq 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, before Vaccination 2 and 1 Month |
|-----------------|---|

End point description:

Percentage of subjects achieving rSBA Titers $\geq 1:128$ for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2 in subjects who received vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 EIP: subjects enrolled and eligible through 1 month after vaccination2; received vaccine at V 1 and V3; blood drawn for assay testing within time frames at Month0 (V1; before dose 1) and at 1 month after dose2 (V4: window 28-42 days); at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviation through V4. Here, N=subjects evaluable for this endpoint and n=subjects evaluable for specified row.

End point type Secondary

End point timeframe:

At baseline (before vaccination 1), 1 month after vaccination 1, before vaccination 2 and 1 month after vaccination 2

| End point values | Nimenrix | | | |
|--|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 128 | | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| MenA, Baseline (Before Vaccination 1), n=128 | 0 (0.0 to 2.8) | | | |
| MenA, 1 Month after Vaccination 1, n=124 | 40.3 (31.6 to 49.5) | | | |
| MenA, Before Vaccination 2, n=125 | 15.2 (9.4 to 22.7) | | | |
| MenA, 1 Month after Vaccination 2, n=128 | 100.0 (97.2 to 100.0) | | | |
| MenC, Baseline (Before Vaccination 1), n=128 | 0.8 (0.0 to 4.3) | | | |
| MenC, 1 Month after Vaccination 1, n=124 | 67.7 (58.8 to 75.9) | | | |
| MenC, Before Vaccination 2, n=125 | 20.8 (14.1 to 29.0) | | | |
| MenC, 1 Month after Vaccination 2, n=128 | 98.4 (94.5 to 99.8) | | | |
| MenW-135, Baseline (Before Vaccination 1), n=128 | 0.8 (0.0 to 4.3) | | | |
| MenW-135, 1 Month after Vaccination 1, n=124 | 79.8 (71.7 to 86.5) | | | |
| MenW-135, Before Vaccination 2, n=125 | 23.2 (16.1 to 31.6) | | | |
| MenW-135, 1 Month after Vaccination 2, n=128 | 100.0 (97.2 to 100.0) | | | |
| MenY, Baseline (Before Vaccination 1), n=128 | 3.9 (1.3 to 8.9) | | | |
| MenY, 1 Month after Vaccination 1, n=124 | 83.1 (75.3 to 89.2) | | | |
| MenY, Before Vaccination 2, n=125 | 27.2 (19.6 to 35.9) | | | |
| MenY, 1 Month after Vaccination 2, n=128 | 99.2 (95.7 to 100.0) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Systematic assessment (SA): local reactions/systemic events recorded within 7 days after Vaccination(Vacc) 1 & 2; Non-SA: SAEs: Day 1 up to 42 days after Vacc 2; other AEs: from Day 1 up to 42 days after Vacc & from Day of Vacc 2 up to 42 days after Vacc2

Adverse event reporting additional description:

Same event may appear as both an non-SAE and SAE. However, what is presented are distinct events. An event may be categorised as serious in one subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event. Safety population was evaluated.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 25.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Nimenrix |
|-----------------------|----------|

Reporting group description:

Participants aged 3 months were administered a single dose of 0.5 milliliter (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1 (Visit 1) and a second dose of Nimenrix (Vaccination 2) at 12 months of age (Visit 3). Participants had a safety follow-up visit 1 month after each vaccination (Visit 2 and Visit 4 respectively).

| Serious adverse events | Nimenrix | | |
|---|------------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 10 / 145 (6.90%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 145 (0.69%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Head injury | | | |
| subjects affected / exposed | 1 / 145 (0.69%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Food protein-induced enterocolitis syndrome | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 1 / 145 (0.69%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 145 (0.69%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 145 (0.69%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 3 / 145 (2.07%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Nimenrix | | |
|---|--------------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 139 / 145 (95.86%) | | |
| Injury, poisoning and procedural complications | | | |
| Head injury | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Nervous system disorders | | | |
| Hypersomnia (INCREASED SLEEP) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|--------------------|--|--|
| subjects affected / exposed | 115 / 145 (79.31%) | | |
| occurrences (all) | 168 | | |
| General disorders and administration site conditions | | | |
| Injection site pain (PAIN AT INJECTION SITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 51 / 145 (35.17%) | | |
| occurrences (all) | 63 | | |
| Swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 12 / 145 (8.28%) | | |
| occurrences (all) | 13 | | |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 31 / 145 (21.38%) | | |
| occurrences (all) | 35 | | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 145 (3.45%) | | |
| occurrences (all) | 5 | | |
| Skin and subcutaneous tissue disorders | | | |
| Erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 32 / 145 (22.07%) | | |
| occurrences (all) | 35 | | |
| Psychiatric disorders | | | |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 119 / 145 (82.07%) | | |
| occurrences (all) | 195 | | |
| Infections and infestations | | | |
| Laryngitis | | | |
| subjects affected / exposed | 4 / 145 (2.76%) | | |
| occurrences (all) | 4 | | |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |

| | | | |
|---|-------------------|--|--|
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 8 / 145 (5.52%) | | |
| occurrences (all) | 8 | | |
| Viral infection | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 7 / 145 (4.83%) | | |
| occurrences (all) | 9 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 3 / 145 (2.07%) | | |
| occurrences (all) | 3 | | |
| Otitis media | | | |
| subjects affected / exposed | 2 / 145 (1.38%) | | |
| occurrences (all) | 2 | | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 65 / 145 (44.83%) | | |
| occurrences (all) | 80 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported