



Clinical trial results:

A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo), Administered to Healthy Individuals 15 through 55 years of age , approximately 4-6 years after primary ACWY vaccination

Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2016-003186-25 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 07 December 2017 |

Results information

| | |
|--------------------------------|--|
| Result version number | v2 (current) |
| This version publication date | 18 August 2018 |
| First version publication date | 20 July 2018 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction of timeframe in adverse events reporting section as per NIH comments. |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 205352 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02986854 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | GlaxoSmithKline Biologicals |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330 |
| Public contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 06 April 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 July 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 07 December 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination
2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination

Protection of trial subjects:

All subjects were observed for at least 30 minutes after vaccine administration with appropriate medical treatment readily available in case of anaphylaxis. Vaccine was administered by qualified and trained personnel and vaccine was given only to eligible subjects that had no contraindications to any components of the vaccine. Subjects were followed for 6 months for selected safety assessments.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 08 December 2016 |
| 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 States: 694 |
| Country: Number of subjects enrolled | Puerto Rico: 10 |
| Worldwide total number of subjects | 704 |
| 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) | 0 |
| Children (2-11 years) | 0 |

| | |
|---------------------------|-----|
| Adolescents (12-17 years) | 480 |
| Adults (18-64 years) | 224 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 1 center in Puerto Rico and 37 centers in Unites States.

Pre-assignment

Screening details:

704 subjects were enrolled in this study. Out of 704 enrolled, 701 received the study vaccine.

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 704 |
| Number of subjects completed | 701 |

Pre-assignment subject non-completion reasons

| | |
|----------------------------|-------------------|
| Reason: Number of subjects | Not randomized: 3 |
|----------------------------|-------------------|

Period 1

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

Blinding implementation details:

The study was an open-labelled study. Therefore, no blinding procedures were utilized.

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|---------------------|
| Arm title | Menveo-Menveo Group |
|------------------|---------------------|

Arm description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solution for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

| | |
|------------------|-----------------------|
| Arm title | Menactra-Menveo Group |
|------------------|-----------------------|

Arm description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solution for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

| | |
|---|--|
| Arm title | Naive Group |
| Arm description: Healthy subjects, 15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1. | |
| Arm type | Control |
| Investigational medicinal product name | Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Powder and solution for solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

| Number of subjects in period 1^[1] | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group |
|---|---------------------|-----------------------|-------------|
| Started | 301 | 300 | 100 |
| Completed | 298 | 288 | 97 |
| Not completed | 3 | 12 | 3 |
| Consent withdrawn by subject | - | 1 | 1 |
| Lost to follow-up | 3 | 11 | 2 |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Number of subjects reported in the baseline period are subjects who received vaccination (exposed set). Out of 704 subjects enrolled worldwide, 3 subjects were not randomized into any group and therefore did not receive any vaccination

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | Menveo-Menveo Group |
|-----------------------|---------------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| | |
|-----------------------|-----------------------|
| Reporting group title | Menactra-Menveo Group |
|-----------------------|-----------------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| | |
|-----------------------|-------------|
| Reporting group title | Naive Group |
|-----------------------|-------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.

| Reporting group values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group |
|---|---------------------|-----------------------|-------------|
| Number of subjects | 301 | 300 | 100 |
| Age categorical Units: Subjects | | | |
| Adolescents | 247 | 228 | 4 |
| Adults | 54 | 72 | 96 |
| Age continuous Units: years | | | |
| arithmetic mean | 17.1 | 17.9 | 38.8 |
| standard deviation | ± 3.66 | ± 4.54 | ± 10.47 |
| Gender categorical Units: Subjects | | | |
| Female | 144 | 156 | 68 |
| Male | 157 | 144 | 32 |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 2 | 6 | 1 |
| Asian | 4 | 14 | 3 |
| Black or African American | 24 | 23 | 12 |
| Native Hawaiian or other Pacific Islander | 3 | 1 | 0 |
| Unspecified | 17 | 23 | 5 |
| White | 251 | 233 | 79 |

| Reporting group values | Total | | |
|------------------------------------|-------|--|--|
| Number of subjects | 701 | | |
| Age categorical Units: Subjects | | | |
| Adolescents | 479 | | |
| Adults | 222 | | |

| | | | |
|---|-----|--|--|
| Age continuous Units: years arithmetic mean standard deviation | - | | |
| Gender categorical Units: Subjects | | | |
| Female | 368 | | |
| Male | 333 | | |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 9 | | |
| Asian | 21 | | |
| Black or African American | 59 | | |
| Native Hawaiian or other Pacific Islander | 4 | | |
| Unspecified | 45 | | |
| White | 563 | | |

End points

End points reporting groups

| | |
|--|--|
| Reporting group title | Menveo-Menveo Group |
| Reporting group description: | |
| Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1. | |
| Reporting group title | Menactra-Menveo Group |
| Reporting group description: | |
| Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1. | |
| Reporting group title | Naive Group |
| Reporting group description: | |
| Healthy subjects, 15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1. | |
| Subject analysis set title | pooled group (menveo-menveo and menactra-menveo) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: | |
| Pooled subjects from both Menveo-Menveo and Menactra-Menveo Groups | |

Primary: Percentages of subjects with human Serum Bactericidal Antibody (hSBA) seroresponse against Neisseria meningitidis serogroups A, C, W and Y.

| | |
|---|---|
| End point title | Percentages of subjects with human Serum Bactericidal Antibody (hSBA) seroresponse against Neisseria meningitidis serogroups A, C, W and Y. |
| End point description: | |
| Seroresponse was defined as follows: for subjects with pre-vaccination hSBA titers < 4, postvaccination hSBA titers ≥ 16; for subjects with pre-vaccination hSBA titers ≥ 4, post vaccination hSBA titers of at least 4 times the pre-vaccination titers. Criteria to demonstrate primary objectives: Immune response sufficiency was tested sequentially; first in the group of subjects who received primary vaccination with Menveo &, if met, also in group of subjects who received primary vaccination with Menactra. Immune response is considered sufficient if lower limit of the 1-sided 97.5% CI for percentage of subjects with hSBA seroresponse against serogroups A, C, W & Y is greater than 75%. Study is considered successful if immune response sufficiency is demonstrated at least in group of subjects who received primary vaccination with Menveo. This outcome measure was assessed only on subjects from Menveo-Menveo & Menactra-Menveo groups. Data from pooled and Naive groups are presented as part of secondary objectives | |
| End point type | Primary |
| End point timeframe: | |
| At Day 29 | |

| End point values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group | pooled group (menveo-menveo and menactra-menveo) |
|--|------------------------|------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 571 |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men A, Pre < 4 (N=246,234,85,480) | 97.97 (95.32 to 99.34) | 97.01 (93.93 to 98.79) | 64.71 (53.59 to 74.77) | 97.50 (95.67 to 98.70) |

| | | | | |
|--|------------------------|------------------------|------------------------|------------------------|
| hSBA-Men A, Pre \geq 4(N-43,48,8,91) | 88.37 (74.92 to 96.11) | 93.75 (82.8 to 98.69) | 75.00 (34.91 to 96.81) | 91.21 (83.41 to 96.13) |
| hSBA-Men A, Total seroresponse(N-289,282,93,571) | 96.54 (93.73 to 98.33) | 96.45 (93.58 to 98.29) | 65.59 (55.02 to 75.14) | 96.50 (94.64 to 97.85) |
| hSBA-Men C, Pre < 4(N-85,103,43,188) | 100 (95.75 to 100) | 100 (96.48 to 100) | 55.81 (39.88 to 70.92) | 100 (98.06 to 100) |
| hSBA-Men C, Pre \geq 4(N-203,177,50,380) | 93.6 (89.3 to 96.55) | 93.79 (89.15 to 96.86) | 58.00 (43.21 to 71.81) | 93.68 (90.75 to 95.91) |
| hSBA-Men C, Total seroresponse(N-288,280,93,568) | 95.49 (92.4 to 97.57) | 96.07 (93.08 to 98.02) | 56.99 (46.31 to 67.22) | 95.77 (93.78 to 97.27) |
| hSBA-Men W, Pre < 4(N-52,58,33,110) | 100 (93.15 to 100) | 100 (93.84 to 100) | 54.55 (36.35 to 71.89) | 100 (96.70 to 100) |
| hSBA-Men W, Pre \geq 4(N-237,223,59,460) | 94.94 (91.32 to 97.36) | 91.48 (87.01 to 94.79) | 25.42 (14.98 to 38.44) | 93.26 (90.57 to 95.38) |
| hSBA-Men W, Total seroresponse(N-289,281,92,570) | 95.85 (92.86 to 97.84) | 93.24 (89.64 to 95.88) | 35.87 (26.13 to 46.54) | 94.56 (92.37 to 96.28) |
| hSBA-Men Y, Pre < 4(N-115,123,54,238) | 100 (96.84 to 100) | 97.56 (93.04 to 99.49) | 55.56 (41.40 to 69.08) | 98.74 (96.36 to 99.74) |
| hSBA-Men Y, Pre \geq 4(N-172,157,39,329) | 94.77 (90.3 to 97.58) | 91.72 (86.26 to 95.52) | 46.15 (30.09 to 62.82) | 93.31 (90.05 to 95.76) |
| hSBA-Men Y, Total seroresponse(N-287,280,93,567) | 96.86 (94.13 to 98.56) | 94.29 (90.89 to 96.7) | 51.61 (41.01 to 62.11) | 95.59 (93.56 to 97.13) |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|---|-----------------------------------|
| Statistical analysis description: | |
| Serogroup A-day 29-Total seroresponse (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[1] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 30.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.76 |
| upper limit | 41.25 |

Notes:

[1] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 2 |
|---|-------------------------------------|
| Statistical analysis description: | |
| Serogroup A-day 29-Total seroresponse (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[2] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 30.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.66 |
| upper limit | 41.17 |

Notes:

[2] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup A-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[3] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 30.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.89 |
| upper limit | 41.12 |

Notes:

[3] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 4 |
| Statistical analysis description: | |
| Serogroup A- DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[4] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 0.09 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.15 |
| upper limit | 3.36 |

Notes:

[4] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

| Statistical analysis title | Statistical analysis 5 |
|---|-----------------------------------|
| Statistical analysis description: | |
| Serogroup C-day 29-Total seroresponse (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[5] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 38.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 28.54 |
| upper limit | 48.9 |

Notes:

[5] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 6 |
|---|-------------------------------------|
| Statistical analysis description: | |
| Serogroup C-day 29-Total seroresponse (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[6] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 39.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 29.16 |
| upper limit | 49.46 |

Notes:

[6] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 7 |
|--|--|
| Statistical analysis description: | |
| Serogroup C-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[7] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 38.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 29.03 |
| upper limit | 49.06 |

Notes:

[7] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8 |
| Statistical analysis description: | |
| Serogroup C-DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[8] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | -0.59 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.12 |
| upper limit | 2.92 |

Notes:

[8] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 9 |
| Statistical analysis description: | |
| Serogroup W-day 29-Total seroresponse (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[9] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 59.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 49.49 |
| upper limit | 69.32 |

Notes:

[9] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 10 |
| Statistical analysis description: | |
| Serogroup W-day 29-Total seroresponse (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[10] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 57.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 46.71 |
| upper limit | 66.88 |

Notes:

[10] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 11 |
| Statistical analysis description: | |
| Serogroup W-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[11] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 58.69 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 48.32 |
| upper limit | 67.94 |

Notes:

[11] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup W-DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[12] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 2.61 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.17 |
| upper limit | 6.62 |

Notes:

[12] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 13 |
| Statistical analysis description: | |
| Serogroup Y-day 29-Total seroresponse (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[13] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 45.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 35.11 |
| upper limit | 55.47 |

Notes:

[13] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup Y-day 29-Total seroresponse (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[14] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 42.67 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 32.34 |
| upper limit | 53.04 |

Notes:

[14] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup Y-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[15] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 43.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 33.92 |
| upper limit | 54.14 |

Notes:

[15] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup Y- DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[16] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Difference in percentages |
| Point estimate | 2.58 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.86 |
| upper limit | 6.3 |

Notes:

[16] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Number of subjects reporting any unsolicited adverse events (AEs)

| | |
|-----------------|---|
| End point title | Number of subjects reporting any unsolicited adverse events (AEs) |
|-----------------|---|

End point description:

An AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom , or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product. An unsolicited adverse event is an adverse event that was not solicited using a subject diary and that was spontaneously communicated by a subject and/or parent(s)/legal guardian(s) who has signed the informed consent.

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

End point timeframe:

Within 30 minutes after vaccination

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|-----------------------------|-------------------------|---------------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 301 | 300 | 100 | 601 |
| Units: Participants | | | | |
| Any Unsolicited AEs | 0 | 8 | 1 | 8 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting solicited local and systemic AEs

| | |
|--|---|
| End point title | Number of subjects reporting solicited local and systemic AEs |
| End point description: Assessed solicited local symptoms were injection site pain, erythema, induration. Assessed solicited systemic symptoms were fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever [defined and measured by a body temperature ≥ 37.5 degrees Celsius ($^{\circ}\text{C}$)]. Threshold for Erythema and Induration: Grade 0 (<25 mm), Any (≥ 25 mm) | |
| End point type | Secondary |
| End point timeframe: From Day 1 (6 hours) through Day 7 after vaccination | |

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|-------------------------|---------------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 296 | 296 | 97 | 592 |
| Units: Participants | | | | |
| Any Local symptom(N-296,296,97,592) | 119 | 97 | 41 | 216 |
| Any Systemic symptom(N-296,296,97,592) | 162 | 148 | 35 | 310 |
| Any Induration(N-286,286,92,592) | 15 | 9 | 8 | 24 |
| Any Erythema(N-286,287,92,573) | 12 | 8 | 10 | 20 |
| Any Pain(N-292,296,97,588) | 114 | 96 | 40 | 210 |
| Any Nausea(N-294,294,97,588) | 48 | 44 | 13 | 92 |
| Any Fatigue(N-295,296,97,591) | 113 | 110 | 19 | 223 |
| Any Myalgia(N-294,296,97,590) | 55 | 54 | 15 | 109 |
| Any Arthralgia(N-294,295,96,589) | 44 | 38 | 13 | 82 |
| Any Headache(N-294,295,97,589) | 100 | 82 | 21 | 182 |
| Any loss of apetite(N-294,296,97,590) | 37 | 46 | 6 | 83 |
| Any chills(N-294,295,97,589) | 34 | 35 | 10 | 69 |
| Fever(N-296,296,97,592) | 2 | 5 | 0 | 7 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting other indicators of reactogenicity

| | |
|-----------------|---|
| End point title | Number of subjects reporting other indicators of reactogenicity |
|-----------------|---|

End point description:

Assessed indicators of reactogenicity were use of analgesics/antipyretics for prophylaxis, use of analgesics/antipyretics for treatment, body temperature (described as 0.5 °C increments from ≥ 36.0°C)

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

End point timeframe:

From Day 1 (6 hours) through Day 7 after vaccination

| End point values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group | pooled group (menveo-menveo and menactra-menveo) |
|---|---------------------|-----------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 296 | 296 | 97 | 592 |
| Units: Participants | | | | |
| Analgesic/antipyretic-prophylaxis(N-294,295,96,589) | 13 | 15 | 5 | 28 |
| Analgesic/antipyretic-treatment(N-293,295,96,588) | 18 | 24 | 10 | 42 |
| Body temp(36.0 - 36.4 °C)(N-296,296,97,592) | 68 | 57 | 16 | 125 |
| Body temp (36.5 - 36.9 °C)(N-296,296,97,592) | 135 | 141 | 45 | 276 |
| Body temp (37.0 - 37.4 °C)(N-296,296,97,592) | 83 | 77 | 33 | 160 |
| Body temp (37.5 - 37.9 °C)(N-296,296,97,592) | 6 | 9 | 3 | 15 |
| Body temp (38.0 - 38.4 °C)(N-296,296,97,592) | 1 | 2 | 0 | 3 |
| Body temp (38.5 - 38.9 °C)(N-296,296,97,592) | 1 | 3 | 0 | 4 |
| Body temp (39.0 - 39.4 °C)(N-296,296,97,592) | 0 | 0 | 0 | 0 |
| Body temp (39.5 - 39.9 °C)(N-296,296,97,592) | 0 | 0 | 0 | 0 |
| Body temp (≥40°C)(N-296,296,97,592) | 0 | 0 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting all unsolicited AEs

| | |
|-----------------|--|
| End point title | Number of subjects reporting all unsolicited AEs |
|-----------------|--|

End point description:

An AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product. An unsolicited adverse event was an adverse event that was not solicited using a subject diary and that was spontaneously communicated by a subject and/or parent(s)/legal guardian(s) who has signed the informed consent.

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

End point timeframe:

From Day 1 through Day 29 after vaccination

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|-----------------------------|-------------------------|---------------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 301 | 300 | 100 | 601 |
| Units: Participants | | | | |
| All unsolicited AEs | 74 | 78 | 22 | 152 |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting medically-attended AEs (MAAEs), AEs leading to withdrawal and serious AEs (SAEs)

| | |
|-----------------|---|
| End point title | Number of subjects reporting medically-attended AEs (MAAEs), AEs leading to withdrawal and serious AEs (SAEs) |
|-----------------|---|

End point description:

Medically attended AEs were defined as symptoms or illnesses requiring hospitalization, or emergency room visit, or visit to/by a health care provider. SAE was defined as any untoward medical occurrence that at any dose resulted in: death, was life-threatening, required or prolonged hospitalization, persistent or significant disability/incapacity, congenital anomaly/or birth defect, an important and significant medical event that might not have been immediately life threatening or resulting in death or hospitalization but, based upon appropriate medical judgment, might jeopardized the subject or might required intervention to prevent one of the other outcomes listed.

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

End point timeframe:

From Day 1 through Day 181 (entire study period)

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|-------------------------------|-------------------------|---------------------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 301 | 300 | 100 | 601 |
| Units: Participants | | | | |
| Any MAAEs | 102 | 79 | 19 | 181 |
| Any AEs leading to withdrawal | 0 | 0 | 0 | 0 |
| Any SAEs | 3 | 2 | 3 | 5 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup A

| | |
|--|--|
| End point title | Percentages of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup A |
| End point description: For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 8 and associated two-sided 95% CIs were calculated. | |
| End point type | Secondary |
| End point timeframe: At Day 1 (pre-vaccination), Day 4, Day 6 and Day 29 | |

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|-------------------------|---------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 572 |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men A ≥ 8 , Day 1(N-289,282,93,571) | 12.46 (8.88 to 16.83) | 14.89 (10.95 to 19.59) | 4.3 (1.18 to 10.65) | 13.66 (10.95 to 16.75) |
| hSBA-Men A ≥ 8 , Day 4(N-144,138,48,282) | 11.11 (6.49 to 17.42) | 13.04 (7.92 to 19.83) | 4.17 (0.51 to 14.25) | 12.06 (8.5 to 16.44) |
| hSBA-Men A ≥ 8 , Day 6(N-146,140,44,286) | 53.42 (44.99 to 61.71) | 47.14 (38.66 to 55.75) | 9.09 (2.53 to 21.67) | 50.35 (44.4 to 56.29) |
| hSBA-Men A ≥ 8 , Day 29(N-290,282,93,572) | 98.62 (96.51 to 99.62) | 98.94 (96.92 to 99.78) | 70.97 (60.64 to 79.92) | 98.78 (97.49 to 99.51) |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Statistical analysis 1 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[17] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 8.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.23 |
| upper limit | 13.41 |

Notes:

[17] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[18] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between group differences in percentage |
| Point estimate | 10.59 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.54 |
| upper limit | 16.14 |

Notes:

[18] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Pooled Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[19] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between group differences in percentage |
| Point estimate | 9.36 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.72 |
| upper limit | 13.58 |

Notes:

[19] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

| | |
|--|---|
| Statistical analysis title | Statistical analysis 4 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[20] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between group differences in percentage |
| Point estimate | -2.44 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.17 |
| upper limit | 3.24 |

Notes:

[20] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

| | |
|--|--|
| Statistical analysis title | Statistical analysis 5 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[21] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 6.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.57 |
| upper limit | 14.15 |

Notes:

[21] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-------------------------------------|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |

| | |
|---|--|
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[22] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 8.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.77 |
| upper limit | 16.52 |

Notes:

[22] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 7 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[23] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 7.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.34 |
| upper limit | 13.48 |

Notes:

[23] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 8 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[24] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -1.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.84 |
| upper limit | 5.82 |

Notes:

[24] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 9 |
|--|--|
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[25] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 44.33 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 30.25 |
| upper limit | 54.6 |

Notes:

[25] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 10 |
|--|--|
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[26] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 38.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 23.93 |
| upper limit | 48.58 |

Notes:

[26] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 11 |
|---|--|
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|--|
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[27] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 41.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 28.15 |
| upper limit | 49.72 |

Notes:

[27] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[28] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 6.28 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.31 |
| upper limit | 17.71 |

Notes:

[28] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 13 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[29] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 27.65 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.25 |
| upper limit | 37.65 |

Notes:

[29] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[30] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 27.97 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.6 |
| upper limit | 37.95 |

Notes:

[30] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[31] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 27.81 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.5 |
| upper limit | 37.76 |

Notes:

[31] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[32] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -0.32 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.56 |
| upper limit | 1.86 |

Notes:

[32] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup C

| | |
|-----------------|--|
| End point title | Percentages of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup C |
|-----------------|--|

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 8 and associated two-sided 95%CIs were calculated.

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

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|-------------------------|---------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 281 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men C ≥ 8 , Day 1(N-288,281,93,569) | 61.11 (55.22 to 66.77) | 53.74 (47.72 to 59.68) | 33.33 (23.89 to 43.87) | 57.47 (53.29 to 61.57) |
| hSBA-Men C ≥ 8 , Day 4 (N-144,138,48,282) | 70.83 (62.68 to 78.1) | 60.14 (51.47 to 68.38) | 43.75 (29.48 to 58.82) | 65.6 (59.74 to 71.13) |
| hSBA-Men C ≥ 8 , Day 6(N-145,139,44,284) | 87.59 (81.09 to 92.47) | 92.09 (86.28 to 95.98) | 43.18 (28.35 to 58.97) | 89.79 (85.66 to 93.05) |
| hSBA-Men C ≥ 8 , Day 29(N-290,281,93,571) | 100 (98.74 to 100) | 99.64 (98.03 to 99.99) | 87.1 (78.55 to 93.15) | 99.82 (99.03 to 100) |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[33] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 27.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16.23 |
| upper limit | 38.27 |

Notes:

[33] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[34] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 20.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.78 |
| upper limit | 31.03 |

Notes:

[34] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[35] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 24.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 13.28 |
| upper limit | 33.86 |

Notes:

[35] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 4 |
|--|---|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[36] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 7.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.76 |
| upper limit | 15.42 |

Notes:

[36] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 5 |
|--|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[37] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 27.08 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 11.04 |
| upper limit | 42.14 |

Notes:

[37] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 6 |
|--|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[38] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 16.39 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.04 |
| upper limit | 31.9 |

Notes:

[38] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 7 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[39] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 21.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.73 |
| upper limit | 36.11 |

Notes:

[39] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 8 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[40] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 10.69 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.42 |
| upper limit | 21.6 |

Notes:

[40] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 9 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[41] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 44.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 28.65 |
| upper limit | 58.93 |

Notes:

[41] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 10 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[42] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 48.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 33.45 |
| upper limit | 63.13 |

Notes:

[42] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 11 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[43] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 46.61 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 31.52 |
| upper limit | 60.59 |

Notes:

[43] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 12 |
|--|---|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[44] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -4.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.84 |
| upper limit | 2.69 |

Notes:

[44] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 13 |
|---|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[45] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 12.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.53 |
| upper limit | 21.22 |

Notes:

[45] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 14 |
|---|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[46] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 12.55 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.1 |
| upper limit | 20.89 |

Notes:

[46] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 15 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[47] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 12.73 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.34 |
| upper limit | 21.05 |

Notes:

[47] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 16 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[48] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.96 |
| upper limit | 1.99 |

Notes:

[48] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentage of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup W

| | |
|-----------------|---|
| End point title | Percentage of subjects with hSBA titer ≥ 8 against N. meningitidis serogroup W |
|-----------------|---|

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 8 and associated two-sided 95% CIs were calculated.

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

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|---------------------------|---------------------------|---------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men W ≥ 8 , Day 1(N- 289,282,93,571) | 75.43 (70.05 to 80.29) | 76.95 (71.59 to 81.74) | 61.29 (50.62 to 71.22) | 76.18 (72.47 to 79.62) |
| hSBA-Men W ≥ 8 , Day 4(144,138,48,282) | 81.94 (74.67 to 87.85) | 82.61 (75.24 to 88.53) | 62.5 (47.35 to 76.05) | 82.27 (77.3 to 86.54) |
| hSBA-Men W ≥ 8 , Day 6(N- 146,140,44,286) | 93.84 (88.62 to 97.14) | 97.86 (93.87 to 99.56) | 63.64 (47.77 to 77.59) | 95.8 (92.79 to 97.81) |
| hSBA-Men W ≥ 8 , Day 29(N- 290,281,92,571) | 100 (98.74 to 100) | 100 (98.7 to 100) | 84.78 (75.79 to 91.42) | 100 (99.36 to 100) |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Menveo-Menveo Group v Naive Group |
|-------------------|-----------------------------------|

| | |
|---|-----|
| Number of subjects included in analysis | 383 |
|---|-----|

| | |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

| | |
|---------------|-----------------------|
| Analysis type | other ^[49] |
|---------------|-----------------------|

| | |
|--------|-----------------------------------|
| Method | Miettinen & Nurminen score method |
|--------|-----------------------------------|

| | |
|--------------------|--|
| Parameter estimate | Between groups differences in percentage |
|--------------------|--|

| | |
|----------------|-------|
| Point estimate | 14.14 |
|----------------|-------|

Confidence interval

| | |
|-------|------|
| level | 95 % |
|-------|------|

| | |
|-------|---------|
| sides | 2-sided |
|-------|---------|

| | |
|-------------|------|
| lower limit | 3.46 |
|-------------|------|

| | |
|-------------|-------|
| upper limit | 25.39 |
|-------------|-------|

Notes:

[49] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

| | |
|-------------------|-------------------------------------|
| Comparison groups | Menactra-Menveo Group v Naive Group |
|-------------------|-------------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[50] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 15.66 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5 |
| upper limit | 26.89 |

Notes:

[50] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[51] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 14.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.91 |
| upper limit | 25.62 |

Notes:

[51] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[52] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -1.52 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.51 |
| upper limit | 5.5 |

Notes:

[52] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 5 |
|--|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[53] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.44 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.25 |
| upper limit | 34.83 |

Notes:

[53] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 6 |
|--|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[54] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 20.11 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.88 |
| upper limit | 35.5 |

Notes:

[54] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 7 |
|---|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|--|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[55] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.53 |
| upper limit | 34.58 |

Notes:

[55] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[56] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -0.66 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.67 |
| upper limit | 8.4 |

Notes:

[56] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 9 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[57] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 30.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 16.78 |
| upper limit | 45.45 |

Notes:

[57] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 10 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[58] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 34.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.29 |
| upper limit | 49.2 |

Notes:

[58] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 11 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[59] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 32.17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.3 |
| upper limit | 47.13 |

Notes:

[59] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[60] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -4.02 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.45 |
| upper limit | 0.74 |

Notes:

[60] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 13 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[61] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 15.22 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 9.28 |
| upper limit | 23.95 |

Notes:

[61] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 14 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[62] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 15.22 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 9.28 |
| upper limit | 23.95 |

Notes:

[62] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 15 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|-------------------|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
|-------------------|--|

| | |
|---|--|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[63] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 15.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 9.28 |
| upper limit | 23.94 |

Notes:

[63] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[64] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.31 |
| upper limit | 1.35 |

Notes:

[64] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup Y

| | |
|---|--|
| End point title | Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup Y |
| End point description: | |
| For each study group and in the pooled group, percentages of subjects with hSBA titer ≥8 and associated two-sided 95%CIs were calculated. | |
| End point type | Secondary |
| End point timeframe: | |
| At day 1(pre-vaccination), day 4, day 6 and day 29 | |

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|---|-------------------------|---------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 281 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men Y \geq 8, Day 1(N-287,281,93,568) | 54.01 (48.05 to 59.88) | 46.98 (41.02 to 52.99) | 32.26 (22.93 to 42.75) | 50.53 (46.33 to 54.72) |
| hSBA-Men Y \geq 8, Day 4(N-143,138,48,281) | 55.24 (46.71 to 63.56) | 55.8 (47.1 to 64.24) | 33.33 (20.4 to 48.41) | 55.52 (49.5 to 61.42) |
| hSBA-Men Y \geq 8, Day 6(N-145,140,44,285) | 85.52 (78.72 to 90.81) | 87.86 (81.27 to 92.76) | 45.45 (30.39 to 61.15) | 86.67 (82.16 to 90.39) |
| hSBA-Men Y \geq 8, Day 29(N-290,281,93,571) | 100 (98.74 to 100) | 99.64 (98.03 to 99.99) | 77.42 (67.58 to 85.45) | 99.82 (99.03 to 100) |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|--|--|
| Statistical analysis description: Serogroup Y- hSBA titer \geq 8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[65] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 21.75 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10.19 |
| upper limit | 32.25 |

Notes:

[65] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 2 |
|--|--|
| Statistical analysis description: Serogroup Y- hSBA titer \geq 8-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[66] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 14.72 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.15 |
| upper limit | 25.29 |

Notes:

[66] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[67] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 18.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.44 |
| upper limit | 27.92 |

Notes:

[67] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[68] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 7.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.2 |
| upper limit | 15.17 |

Notes:

[68] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[69] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 21.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.57 |
| upper limit | 36.37 |

Notes:

[69] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[70] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.46 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.05 |
| upper limit | 37 |

Notes:

[70] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 7 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[71] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.89 |
| upper limit | 35.38 |

Notes:

[71] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 8 |
|--|---|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[72] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -0.55 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.11 |
| upper limit | 11.03 |

Notes:

[72] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 9 |
|--|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[73] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 40.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.26 |
| upper limit | 54.95 |

Notes:

[73] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 10 |
|--|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[74] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 42.4 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 26.71 |
| upper limit | 57.17 |

Notes:

[74] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 11 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[75] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 41.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 26.12 |
| upper limit | 55.55 |

Notes:

[75] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 12 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[76] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -2.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.41 |
| upper limit | 5.73 |

Notes:

[76] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 13 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[77] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.58 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15.26 |
| upper limit | 32.08 |

Notes:

[77] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[78] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.22 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 14.86 |
| upper limit | 31.74 |

Notes:

[78] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[79] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.41 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15.08 |
| upper limit | 31.9 |

Notes:

[79] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 8 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[80] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.96 |
| upper limit | 1.99 |

Notes:

[80] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup A

| | |
|--|---|
| End point title | Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup A |
| End point description: | |
| For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 16 and associated two-sided 95%CIs were calculated. | |
| End point type | Secondary |
| End point timeframe: | |
| At day 1(pre-vaccination), day 4, day 6 and day 29 | |

| End point values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group | pooled group (menveo-menveo and menactra-menveo) |
|---|------------------------|------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 572 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men A ≥ 16 , Day 1(N-289,282,93,571) | 8.3 (5.39 to 12.1) | 9.57 (6.4 to 13.62) | 1.08 (0.03 to 5.85) | 8.93 (6.72 to 11.58) |
| hSBA-Men A ≥ 16 , Day 4(N-144,138,48,282) | 8.33 (4.38 to 14.1) | 8.7 (4.57 to 14.7) | 2.08 (0.05 to 11.07) | 8.51 (5.53 to 12.4) |
| hSBA-Men A ≥ 16 , Day 6(N-146,140,44,286) | 45.89 (37.62 to 54.33) | 41.43 (33.17 to 50.05) | 4.55 (0.56 to 15.47) | 43.71 (37.87 to 49.67) |
| hSBA-Men A ≥ 16 , Day 29(N-290,282,93,572) | 98.28 (96.02 to 99.44) | 97.52 (94.95 to 99) | 66.67 (56.13 to 76.11) | 97.9 (96.36 to 98.91) |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Statistical analysis 1 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[81] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 7.23 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.08 |
| upper limit | 11.23 |

Notes:

[81] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[82] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 8.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.28 |
| upper limit | 12.74 |

Notes:

[82] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|--|
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[83] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 7.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.87 |
| upper limit | 10.78 |

Notes:

[83] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 4 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[84] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -1.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.1 |
| upper limit | 3.49 |

Notes:

[84] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 5 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[85] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 6.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.04 |
| upper limit | 12.44 |

Notes:

[85] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[86] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 6.61 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.71 |
| upper limit | 13.01 |

Notes:

[86] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 7 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[87] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 6.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.66 |
| upper limit | 10.9 |

Notes:

[87] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[88] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -0.36 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.27 |
| upper limit | 6.43 |

Notes:

[88] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 9 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[89] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 41.34 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 28.85 |
| upper limit | 50.63 |

Notes:

[89] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 10 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[90] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 36.88 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.39 |
| upper limit | 46.34 |

Notes:

[90] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 11 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|-------------------|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
|-------------------|--|

| | |
|---|--|
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[91] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 39.16 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 27.61 |
| upper limit | 46.33 |

Notes:

[91] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[92] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 4.46 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.04 |
| upper limit | 15.83 |

Notes:

[92] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 13 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[93] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 31.61 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.68 |
| upper limit | 41.79 |

Notes:

[93] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[94] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 30.85 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.85 |
| upper limit | 41.08 |

Notes:

[94] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[95] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 31.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.39 |
| upper limit | 41.38 |

Notes:

[95] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup A- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[96] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.76 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.81 |
| upper limit | 3.52 |

Notes:

[96] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup C

| | |
|-----------------|---|
| End point title | Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup C |
|-----------------|---|

End point description:

Analysis was performed on per protocol set for immunogenicity, which included all randomized subjects who had no protocol deviations and were not excluded due to other reasons defined prior to unblinding/analysis, who received study vaccination and provided evaluable serum samples at each time point, with result available for at least 1 serogroup

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

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

| End point values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group | pooled group (menveo-menveo and menactra-menveo) |
|---|------------------------|------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 281 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men C ≥ 16 , Day 1(N-288,281,93,569) | 47.22 (41.34 to 53.16) | 38.08 (32.38 to 44.04) | 17.2 (10.17 to 26.43) | 42.71 (38.6 to 46.89) |
| hSBA-Men C ≥ 16 , Day 4(N-144,138,48,282) | 54.17 (45.67 to 62.49) | 44.93 (36.46 to 53.62) | 29.17 (16.95 to 44.06) | 49.65 (43.66 to 55.64) |
| hSBA-Men C ≥ 16 , Day 6(N-145,139,44,284) | 82.07 (74.84 to 87.94) | 81.29 (73.81 to 87.4) | 31.82 (18.61 to 47.58) | 81.69 (76.69 to 86.01) |
| hSBA-Men C ≥ 16 , Day 29(N-290,281,93,571) | 99.66 (98.09 to 99.99) | 99.64 (98.03 to 99.99) | 69.89 (59.5 to 78.97) | 99.65 (98.74 to 99.96) |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[97] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 30.02 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.55 |
| upper limit | 38.83 |

Notes:

[97] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[98] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 20.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10.48 |
| upper limit | 29.69 |

Notes:

[98] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[99] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 25.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15.79 |
| upper limit | 33.21 |

Notes:

[99] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 4 |
|---|---|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[100] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 9.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.01 |
| upper limit | 17.16 |

Notes:

[100] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 5 |
|---|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[101] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.82 |
| upper limit | 38.9 |

Notes:

[101] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 6 |
|---|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[102] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 15.76 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.44 |
| upper limit | 29.86 |

Notes:

[102] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 7 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[103] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 20.48 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.32 |
| upper limit | 33.08 |

Notes:

[103] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 8 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[104] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 9.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.45 |
| upper limit | 20.68 |

Notes:

[104] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 9 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[105] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 50.25 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 34.09 |
| upper limit | 63.67 |

Notes:

[105] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 10 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[106] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 49.48 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 33.21 |
| upper limit | 63.01 |

Notes:

[106] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 11 |
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[107] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 49.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 34.42 |
| upper limit | 62.6 |

Notes:

[107] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 12 |
|---|---|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[108] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.3 |
| upper limit | 9.92 |

Notes:

[108] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 13 |
|--|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[109] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 29.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.34 |
| upper limit | 39.75 |

Notes:

[109] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 14 |
|--|--|
| Statistical analysis description: | |
| Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[110] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 29.75 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.32 |
| upper limit | 39.74 |

Notes:

[110] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 15 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[111] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 29.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.35 |
| upper limit | 39.73 |

Notes:

[111] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 16 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[112] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 1.67 |

Notes:

[112] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup W

| | |
|-----------------|---|
| End point title | Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup W |
|-----------------|---|

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 16 and associated two-sided 95% CIs were calculated.

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

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|---|--------------------------|---------------------------|---------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men W ≥ 16 , Day 1(N- 289,282,93,571) | 65.74 (59.96 to 71.2) | 66.31 (60.47 to 71.81) | 48.39 (37.89 to 58.99) | 66.02 (61.98 to 69.91) |
| hSBA-Men W ≥ 16 , Day 4(N- 144,138,48,282) | 68.75 (60.5 to 76.21) | 76.81 (68.87 to 83.57) | 54.17 (39.17 to 68.63) | 72.7 (67.1 to 77.81) |
| hSBA-Men W ≥ 16 , Day 6(N- 146,140,44,286) | 89.04 (82.81 to 93.6) | 92.14 (86.38 to 96.01) | 50 (34.56 to 65.44) | 90.56 (86.56 to 93.69) |
| hSBA-Men W ≥ 16 , Day 29(N- 290,281,92,571) | 100 (98.74 to 100) | 100 (98.7 to 100) | 80.43 (70.85 to 87.97) | 100 (99.36 to 100) |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[113] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 17.36 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.85 |
| upper limit | 28.67 |

Notes:

[113] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|----------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

| | |
|-------------------|-------------------------------------|
| Comparison groups | Menactra-Menveo Group v Naive Group |
|-------------------|-------------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[114] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 17.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.39 |
| upper limit | 29.25 |

Notes:

[114] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[115] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 17.64 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.85 |
| upper limit | 28.28 |

Notes:

[115] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[116] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -0.57 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.32 |
| upper limit | 7.2 |

Notes:

[116] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 5 |
|---|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[117] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 14.58 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.98 |
| upper limit | 30.38 |

Notes:

[117] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 6 |
|---|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[118] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 22.64 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.3 |
| upper limit | 38.16 |

Notes:

[118] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 7 |
|--|--|
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |

| | |
|---|--|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[119] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 18.53 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.14 |
| upper limit | 33.37 |

Notes:

[119] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 8 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[120] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -8.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -18.34 |
| upper limit | 2.38 |

Notes:

[120] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 9 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[121] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 39.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 23.76 |
| upper limit | 54.07 |

Notes:

[121] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 10 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[122] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 42.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 27.08 |
| upper limit | 56.98 |

Notes:

[122] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 11 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[123] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 40.56 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.91 |
| upper limit | 55.15 |

Notes:

[123] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[124] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | -3.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.2 |
| upper limit | 3.89 |

Notes:

[124] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 13 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[125] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.57 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.74 |
| upper limit | 28.83 |

Notes:

[125] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 14 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[126] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.57 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.74 |
| upper limit | 28.83 |

Notes:

[126] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 15 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|-------------------|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
|-------------------|--|

| | |
|---|--|
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[127] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.57 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.75 |
| upper limit | 28.83 |

Notes:

[127] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 16 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[128] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.31 |
| upper limit | 1.35 |

Notes:

[128] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup Y

| | |
|-----------------|---|
| End point title | Percentages of subjects with hSBA titer ≥ 16 against N. meningitidis serogroup Y |
|-----------------|---|

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥ 16 and associated two-sided 95%CIs were calculated.

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

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|-------------------------|---------------------------|------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 281 | 93 | 571 |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men Y \geq 16, Day 1(N-287,281,93,568) | 39.02 (33.35 to 44.93) | 34.88 (29.31 to 40.76) | 17.2 (10.17 to 26.43) | 36.97 (32.99 to 41.09) |
| hSBA-Men Y \geq 16, Day 4(N-143,138,48,281) | 39.16 (31.11 to 47.67) | 39.13 (30.94 to 47.8) | 20.83 (10.47 to 34.99) | 39.15 (33.4 to 45.12) |
| hSBA-Men Y \geq 16, Day 6(N-145,140,44,285) | 80.69 (73.31 to 86.77) | 80 (72.41 to 86.28) | 31.82 (18.61 to 47.58) | 80.35 (75.26 to 84.8) |
| hSBA-Men Y \geq 16, Day 29(N-290,281,93,571) | 100 (98.74 to 100) | 98.58 (96.4 to 99.61) | 64.52 (53.91 to 74.17) | 99.3 (98.22 to 99.81) |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|--|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer \geq 16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[129] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 21.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 11.44 |
| upper limit | 30.6 |

Notes:

[129] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 2 |
|--|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer \geq 16-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[130] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 17.67 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.34 |
| upper limit | 26.43 |

Notes:

[130] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[131] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 19.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 10.09 |
| upper limit | 27.43 |

Notes:

[131] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[132] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 4.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.8 |
| upper limit | 12.04 |

Notes:

[132] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naive Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[133] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 18.33 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.92 |
| upper limit | 30.99 |

Notes:

[133] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|--|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[134] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 18.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.83 |
| upper limit | 31.06 |

Notes:

[134] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 7 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[135] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 18.31 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.83 |
| upper limit | 29.39 |

Notes:

[135] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 8 |
|---|---|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[136] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.35 |
| upper limit | 11.39 |

Notes:

[136] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 9 |
|---|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[137] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 48.87 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 32.64 |
| upper limit | 62.38 |

Notes:

[137] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| Statistical analysis title | Statistical analysis 10 |
|---|--|
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[138] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 48.18 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 31.87 |
| upper limit | 61.79 |

Notes:

[138] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 11 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

| | |
|---|--|
| Comparison groups | Naïve Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[139] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 48.53 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 33.04 |
| upper limit | 61.31 |

Notes:

[139] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 12 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

| | |
|---|---|
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[140] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 0.69 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.6 |
| upper limit | 10.04 |

Notes:

[140] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 13 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Naïve)

| | |
|-------------------|-----------------------------------|
| Comparison groups | Naïve Group v Menveo-Menveo Group |
|-------------------|-----------------------------------|

| | |
|---|--|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[141] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 35.48 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 26.5 |
| upper limit | 45.62 |

Notes:

[141] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 14 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 374 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[142] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 34.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.94 |
| upper limit | 44.28 |

Notes:

[142] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 15 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[143] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 34.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.78 |
| upper limit | 44.93 |

Notes:

[143] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup Y- hSBA titer ≥ 16 -Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menactra-Menveo Group v Menveo-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[144] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Between groups differences in percentage |
| Point estimate | 1.42 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.1 |
| upper limit | 3.6 |

Notes:

[144] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y

| | |
|---|---|
| End point title | Percentages of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y |
| End point description: | |
| Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers < 4 , postvaccination titers ≥ 16 ; for subjects with pre-vaccination titers ≥ 4 , post vaccination titers at least 4 times the pre-vaccination titers. | |
| End point type | Secondary |
| End point timeframe: | |
| At Day 4 and Day 6 | |

| End point values | Menveo-Menveo Group | Menactra-Menveo Group | Naive Group | pooled group (menveo-menveo and menactra-menveo) |
|---|------------------------|------------------------|----------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 289 | 282 | 93 | 571 |
| Units: Percentages of subjects | | | | |
| number (confidence interval 95%) | | | | |
| hSBA-Men A, Pre < 4 , Day 4(N-123,117,45,240) | 0.81 (0.02 to 4.45) | 2.56 (0.53 to 7.31) | 0 (0 to 7.87) | 1.67 (0.46 to 4.21) |
| hSBA-Men A, Pre ≥ 4 , Day 4(N-21,21,3,42) | 4.76 (0.12 to 23.82) | 0 (0 to 16.11) | 0 (0 to 70.76) | 2.38 (0.06 to 12.57) |
| hSBA-Men A, Total seroresponse, Day 4(144,138,48,282) | 1.39 (0.17 to 4.93) | 2.17 (0.45 to 6.22) | 0 (0 to 7.4) | 1.77 (0.58 to 4.09) |
| hSBA-Men A, Pre < 4 , Day 6(N-123,113,39,236) | 39.84 (31.12 to 49.05) | 33.63 (25.01 to 43.12) | 2.56 (0.06 to 13.48) | 36.86 (30.7 to 43.37) |

| | | | | |
|---|------------------------|------------------------|-----------------------|------------------------|
| hSBA-Men A, Pre \geq 4, Day 6(N-22,27,5,49) | 36.36 (17.2 to 59.34) | 22.22 (8.62 to 42.26) | 20 (0.51 to 71.64) | 28.57 (16.58 to 43.26) |
| hSBA-Men A,Total seroresponse,Day 6(145,140,44,285) | 39.31 (31.31 to 47.76) | 31.43 (23.85 to 39.81) | 4.55 (0.56 to 15.47) | 35.44 (29.89 to 41.3) |
| hSBA-Men C, Pre < 4, Day 4(N-36,51,20,87) | 0 (0 to 9.74) | 9.8 (3.26 to 21.41) | 5 (0.13 to 24.87) | 5.75 (1.89 to 12.9) |
| hSBA-Men C, Pre \geq 4, Day 4(N-107,86,28,193) | 3.74 (1.03 to 9.3) | 8.14 (3.34 to 16.05) | 7.14 (0.88 to 23.5) | 5.7 (2.88 to 9.97) |
| hSBA-Men C,Total seroresponse,Day 4(143,137,48,280) | 2.8 (0.77 to 7.01) | 8.76 (4.61 to 14.8) | 6.25 (1.31 to 17.2) | 5.71 (3.3 to 9.11) |
| hSBA-Men C, Pre < 4, Day 6(N-49,51,23,100) | 65.31 (50.36 to 78.33) | 64.71 (50.07 to 77.57) | 13.04 (2.78 to 33.59) | 65 (54.82 to 74.27) |
| hSBA-Men C, Pre \geq 4, Day 6(N-95,88,21,183) | 44.21 (34.02 to 54.77) | 38.64 (28.44 to 49.62) | 9.52 (1.17 to 30.38) | 41.53 (34.31 to 49.03) |
| hSBA-Men C,Total seroresponse,Day 6(144,139,44,283) | 51.39 (42.92 to 59.8) | 48.2 (39.65 to 56.83) | 11.36 (3.79 to 24.56) | 49.82 (43.85 to 55.8) |
| hSBA-Men W, Pre < 4, Day 4(N-21,30,17,51) | 9.52 (1.17 to 30.38) | 30 (14.73 to 49.4) | 11.76 (1.46 to 36.44) | 21.57 (11.29 to 35.32) |
| hSBA-Men W, Pre \geq 4, Day 4(N-123,108,31,231) | 1.63 (0.2 to 5.75) | 4.63 (1.52 to 10.47) | 3.23 (0.08 to 16.7) | 3.03 (1.23 to 6.14) |
| hSBA-Men W,Total seroresponse,Day 4(144,138,48,282) | 2.78 (0.76 to 6.96) | 10.14 (5.66 to 16.44) | 6.25 (1.31 to 17.2) | 6.38 (3.83 to 9.9) |
| hSBA-Men W, Pre < 4, Day 6(N-31,28,16,59) | 64.52 (45.37 to 80.77) | 75 (55.13 to 89.31) | 25 (7.27 to 52.38) | 69.49 (56.13 to 80.81) |
| hSBA-Men W, Pre \geq 4, Day 6(N-114,112,28,226) | 46.49 (37.1 to 56.07) | 42.86 (33.55 to 52.55) | 3.57 (0.09 to 18.35) | 44.69 (38.09 to 51.43) |
| hSBA-Men W,Total seroresponse,Day 6(145,140,44,285) | 50.34 (41.93 to 58.75) | 49.29 (40.74 to 57.86) | 11.36 (3.79 to 24.56) | 49.82 (43.87 to 55.78) |
| hSBA-Men Y, Pre < 4, Day 4(N-62,60,27,122) | 8.06 (2.67 to 17.83) | 6.67 (1.85 to 16.2) | 0 (0 to 12.77) | 7.38 (3.43 to 13.54) |
| hSBA-Men Y, Pre \geq 4, Day 4(N-80,77,21,157) | 7.5 (2.8 to 15.61) | 2.6 (0.32 to 9.07) | 0 (0 to 16.11) | 5.1 (2.23 to 9.79) |
| hSBA-Men Y,Total seroresponse,Day 4(142,137,48,279) | 7.75 (3.93 to 13.44) | 4.38 (1.62 to 9.29) | 0 (0 to 7.4) | 6.09 (3.59 to 9.58) |
| hSBA-Men Y, Pre < 4, Day 6(N-52,62,27,114) | 63.46 (48.96 to 76.38) | 75.81 (63.26 to 85.78) | 11.11 (2.35 to 29.16) | 70.18 (60.89 to 78.38) |
| hSBA-Men Y, Pre \geq 4, Day 6(N-91,78,17,169) | 40.66 (30.48 to 51.47) | 42.31 (31.19 to 54.02) | 5.88 (0.15 to 28.69) | 41.42 (33.91 to 49.24) |
| hSBA-Men Y,Total seroresponse,Day 6(143,140,44,283) | 48.95 (40.51 to 57.44) | 57.14 (48.51 to 65.47) | 9.09 (2.53 to 21.67) | 53 (47.01 to 58.94) |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Serogroup A- Day 4- Total seroresponse (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[145] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 1.39 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.08 |
| upper limit | 4.94 |

Notes:

[145] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[146] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 2.17 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.32 |
| upper limit | 6.21 |

Notes:

[146] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[147] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 1.77 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.68 |
| upper limit | 4.09 |

Notes:

[147] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Serogroup A- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)

| | |
|-------------------|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
|-------------------|---|

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[148] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -0.79 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.98 |
| upper limit | 3.01 |

Notes:

[148] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 5 |
| Statistical analysis description: | |
| Serogroup A- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[149] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 34.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.38 |
| upper limit | 44.07 |

Notes:

[149] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup A- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[150] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 26.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 14.67 |
| upper limit | 36.13 |

Notes:

[150] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 7 |
| Statistical analysis description: | |
| Serogroup A- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[151] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 30.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.42 |
| upper limit | 37.97 |

Notes:

[151] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8 |
| Statistical analysis description: | |
| Serogroup A- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[152] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 7.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.25 |
| upper limit | 18.81 |

Notes:

[152] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 9 |
| Statistical analysis description: | |
| Serogroup C- Day 4-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[153] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -3.45 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -14.26 |
| upper limit | 2.35 |

Notes:

[153] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 10 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[154] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 2.51 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.7 |
| upper limit | 9.98 |

Notes:

[154] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 11 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[155] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -0.54 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -11.35 |
| upper limit | 4.9 |

Notes:

[155] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 12 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)

| | |
|-------------------|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
|-------------------|---|

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[156] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -5.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -12.25 |
| upper limit | -0.57 |

Notes:

[156] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 13 |
| Statistical analysis description: | |
| Serogroup C- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[157] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 40.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.37 |
| upper limit | 50.92 |

Notes:

[157] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup C- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[158] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 36.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.14 |
| upper limit | 47.9 |

Notes:

[158] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup C- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[159] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 38.46 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.79 |
| upper limit | 47.57 |

Notes:

[159] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup C- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[160] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 3.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.44 |
| upper limit | 14.73 |

Notes:

[160] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 17 |
| Statistical analysis description: | |
| Serogroup W- Day 4-Total seroresponse- (Menveo-Menveo vs. Naïve) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[161] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -3.47 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -14.28 |
| upper limit | 2.31 |

Notes:

[161] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 18 |
| Statistical analysis description: | |
| Serogroup W- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[162] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 3.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.4 |
| upper limit | 11.6 |

Notes:

[162] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 19 |
| Statistical analysis description: | |
| Serogroup W- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[163] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 0.13 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.7 |
| upper limit | 5.66 |

Notes:

[163] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 20 |
| Statistical analysis description: | |
| Serogroup W- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[164] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -7.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -13.89 |
| upper limit | -1.8 |

Notes:

[164] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 21 |
| Statistical analysis description: | |
| Serogroup W- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[165] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 38.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.35 |
| upper limit | 49.88 |

Notes:

[165] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 22 |
| Statistical analysis description: | |
| Serogroup W- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[166] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 37.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 23.23 |
| upper limit | 48.95 |

Notes:

[166] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 23 |
| Statistical analysis description: | |
| Serogroup W- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[167] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 38.46 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.8 |
| upper limit | 47.56 |

Notes:

[167] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 24 |
| Statistical analysis description: | |
| Serogroup W- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[168] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 1.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.51 |
| upper limit | 12.6 |

Notes:

[168] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 25 |
| Statistical analysis description: | |
| Serogroup Y- Day 4-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[169] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 7.75 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.15 |
| upper limit | 13.36 |

Notes:

[169] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 26 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[170] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 4.38 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.15 |
| upper limit | 9.24 |

Notes:

[170] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 27 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[171] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 6.09 |

Confidence interval

| | |
|-------------|---------|
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.41 |
| upper limit | 9.55 |

Notes:

[171] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 28 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)

| | |
|-------------------|---|
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
|-------------------|---|

| | |
|---|-----------------------------------|
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[172] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 3.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.48 |
| upper limit | 9.54 |

Notes:

[172] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 29 |
| Statistical analysis description: | |
| Serogroup Y- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 382 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[173] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 39.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 25.76 |
| upper limit | 50.29 |

Notes:

[173] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 30 |
| Statistical analysis description: | |
| Serogroup Y- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive) | |
| Comparison groups | Menactra-Menveo Group v Naive Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[174] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 48.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 33.89 |
| upper limit | 58.34 |

Notes:

[174] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|--|--|
| Statistical analysis title | Statistical analysis 31 |
| Statistical analysis description: | |
| Serogroup Y- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 664 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[175] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | 43.91 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 30.79 |
| upper limit | 52.37 |

Notes:

[175] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

| | |
|---|---|
| Statistical analysis title | Statistical analysis 32 |
| Statistical analysis description: | |
| Serogroup Y- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 571 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[176] |
| Method | Miettinen & Nurminen score method |
| Parameter estimate | Differences in percentage |
| Point estimate | -8.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -19.61 |
| upper limit | 3.45 |

Notes:

[176] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: hSBA Geometric Mean Titers (GMTs) against N. meningitidis serogroup A, C, W and Y.

| | |
|---|--|
| End point title | hSBA Geometric Mean Titers (GMTs) against N. meningitidis serogroup A, C, W and Y. |
| End point description: | |
| For each N. meningitidis serogroup A, C, W and Y, unadjusted GMTs were calculated, with their associated two-sided 95% Confidence Interval. | |
| End point type | Secondary |
| End point timeframe: | |
| At Day 1 (pre-vaccination), Day 4, Day 6 and Day 29 | |

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|---|------------------------------------|------------------------------------|--------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 290 | 282 | 93 | 572 |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-Men A, Day 1(N-289,282,93,571) | 2.81 (2.54 to 3.11) | 2.95 (2.67 to 3.27) | 2.27 (1.9 to 2.71) | 2.88 (2.68 to 3.09) |
| hSBA-Men A, Day 4(N-144,138,48,282) | 2.83 (2.43 to 3.29) | 3 (2.57 to 3.51) | 2.25 (1.73 to 2.93) | 2.91 (2.61 to 3.25) |
| hSBA-Men A, Day 6(N-146,140,44,286) | 12.87 (9.63 to 17.19) | 10.17 (7.57 to 13.66) | 2.48 (1.46 to 4.2) | 11.47 (9.32 to 14.1) |
| hSBA-Men A, Day 29(N- 290,282,93,572) | 210.1 (181.07 to 243.78) | 236.69 (203.56 to 275.2) | 32.11 (24.7 to 41.76) | 222.81 (200.43 to 247.7) |
| hSBA-Men C, Day 1(N-288,281,93,569) | 16.11 (13.28 to 19.54) | 10.72 (8.82 to 13.03) | 5.06 (3.6 to 7.1) | 13.17 (11.48 to 15.12) |
| hSBA-Men C, Day 4(N-144,138,48,282) | 22.96 (17.31 to 30.45) | 14.29 (10.71 to 19.07) | 6.69 (4.1 to 10.9) | 18.21 (14.86 to 22.31) |
| hSBA-Men C, Day 6(N-145,139,44,284) | 92.27 (68.91 to 123.56) | 90.06 (66.84 to 121.35) | 6.71 (3.95 to 11.4) | 91.18 (74.04 to 112.3) |
| hSBA-Men C, Day 29(N- 290,281,93,571) | 1159.93 (977.33 to 1376.63) | 1057.66 (888.74 to 1258.68) | 59.7 (44.12 to 80.78) | 1108.42 (981.09 to 1252.27) |
| hSBA-Men W, Day 1(N-289,282,93,571) | 22.07 (18.54 to 26.29) | 23.46 (19.66 to 28) | 12.21 (8.98 to 16.62) | 22.75 (20.09 to 25.76) |
| hSBA-Men W, Day 4(N-144,138,48,282) | 25.9 (20.13 to 33.32) | 33.87 (26.18 to 43.82) | 13.8 (8.92 to 21.35) | 29.53 (24.66 to 35.37) |
| hSBA-Men W, Day 6(N-146,140,44,286) | 112.49 (86.26 to 146.71) | 143.75 (109.61 to 188.54) | 15.98 (9.85 to 25.93) | 126.84 (104.9 to 153.37) |
| hSBA-Men W, Day 29(N- 290,281,92,571) | 1394.65 (1176.59 to 1653.11) | 1883.96 (1585.12 to 2239.15) | 55.31 (40.9 to 74.8) | 1617.11 (1431.93 to 1826.23) |
| hSBA-Men Y, Day 1(N-287,281,93,568) | 9.24 (7.81 to 10.94) | 8.22 (6.93 to 9.75) | 4.56 (3.39 to 6.13) | 8.72 (7.74 to 9.83) |
| hSBA-Men Y, Day 4(N-143,138,48,281) | 10.87 (8.26 to 14.32) | 12.12 (9.16 to 16.04) | 4.63 (2.88 to 7.44) | 11.47 (9.43 to 13.95) |
| hSBA-Men Y, Day 6(N-145,140,44,285) | 63.3 (47.73 to 83.95) | 61.56 (46.18 to 82.05) | 6.44 (3.86 to 10.76) | 62.44 (51.06 to 76.34) |
| hSBA-Men Y, Day 29(N- 290,281,93,571) | 1066.66 (900.67 to 1263.25) | 1007.62 (848.53 to 1196.54) | 37.4 (27.75 to 50.42) | 1037.19 (919.46 to 1169.98) |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|--|-----------------------------------|
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 4(Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[177] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.26 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.7 |

Notes:

[177] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-------------------------------------|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 4(Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[178] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 1.82 |

Notes:

[178] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 4(Pooled Menveo-Menveo and Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[179] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.29 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.97 |
| upper limit | 1.72 |

Notes:

[179] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 4 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[180] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.76 |
| upper limit | 1.17 |

Notes:

[180] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 5 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[181] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 5.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.84 |
| upper limit | 9.47 |

Notes:

[181] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 6 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[182] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 4.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.24 |
| upper limit | 7.5 |

Notes:

[182] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|--|
| Statistical analysis title | Statistical analysis 7 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[183] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 4.62 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.62 |
| upper limit | 8.15 |

Notes:

[183] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 8 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[184] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 1.91 |

Notes:

[184] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 9 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[185] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 6.54 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.84 |
| upper limit | 8.85 |

Notes:

[185] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 10 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup A-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[186] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 7.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.44 |
| upper limit | 9.98 |

Notes:

[186] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 11 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup A-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[187] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 6.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.23 |
| upper limit | 9.21 |

Notes:

[187] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|---|
| Statistical analysis title | Statistical analysis 12 |
| Statistical analysis description: | |
| Serogroup A-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[188] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.89 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.72 |
| upper limit | 1.1 |

Notes:

[188] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 13 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[189] |
| Parameter estimate | between group GMT ratios |
| Point estimate | 3.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.95 |
| upper limit | 6.04 |

Notes:

[189] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 14 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[190] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.21 |
| upper limit | 3.77 |

Notes:

[190] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|--|
| Statistical analysis title | Statistical analysis 15 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[191] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.72 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.6 |
| upper limit | 4.64 |

Notes:

[191] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 16 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[192] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.61 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.07 |
| upper limit | 2.4 |

Notes:

[192] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 17 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[193] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 13.75 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.51 |
| upper limit | 25.19 |

Notes:

[193] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 18 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[194] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 13.42 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.31 |
| upper limit | 24.66 |

Notes:

[194] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 19 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup C-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[195] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 13.59 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.7 |
| upper limit | 24 |

Notes:

[195] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 20 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[196] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.02 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.67 |
| upper limit | 1.56 |

Notes:

[196] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 21 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[197] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 19.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 13.73 |
| upper limit | 27.51 |

Notes:

[197] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-------------------------------------|
| Statistical analysis title | Statistical analysis 22 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[198] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 17.72 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.5 |
| upper limit | 25.12 |

Notes:

[198] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|--|
| Statistical analysis title | Statistical analysis 23 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[199] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 18.57 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 13.4 |
| upper limit | 25.73 |

Notes:

[199] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|---|
| Statistical analysis title | Statistical analysis 24 |
| Statistical analysis description: | |
| Serogroup C-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[200] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.4 |

Notes:

[200] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 25 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[201] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.88 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.13 |
| upper limit | 3.11 |

Notes:

[201] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 26 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[202] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.46 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.48 |
| upper limit | 4.08 |

Notes:

[202] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 27 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[203] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.33 |
| upper limit | 3.44 |

Notes:

[203] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 28 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[204] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.53 |
| upper limit | 1.1 |

Notes:

[204] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 29 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[205] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 7.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.05 |
| upper limit | 12.22 |

Notes:

[205] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 30 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[206] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 8.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.16 |
| upper limit | 15.66 |

Notes:

[206] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|--|
| Statistical analysis title | Statistical analysis 31 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[207] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 7.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.72 |
| upper limit | 13.35 |

Notes:

[207] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 32 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[208] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.54 |
| upper limit | 1.14 |

Notes:

[208] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 33 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[209] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 25.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 17.83 |
| upper limit | 35.65 |

Notes:

[209] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 34 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)

| | |
|---|-------------------------------------|
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[210] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 34.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.06 |
| upper limit | 48.23 |

Notes:

[210] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 35 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup W-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

| | |
|---|--|
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[211] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 29.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 21.09 |
| upper limit | 40.52 |

Notes:

[211] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|---|
| Statistical analysis title | Statistical analysis 36 |
| Statistical analysis description: | |
| Serogroup W-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[212] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.74 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.58 |
| upper limit | 0.94 |

Notes:

[212] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 37 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[213] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.36 |
| upper limit | 4.07 |

Notes:

[213] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-------------------------------------|
| Statistical analysis title | Statistical analysis 38 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[214] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.62 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.51 |
| upper limit | 4.54 |

Notes:

[214] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|--|
| Statistical analysis title | Statistical analysis 39 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[215] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 2.48 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.48 |
| upper limit | 4.14 |

Notes:

[215] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 40 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[216] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.61 |
| upper limit | 1.33 |

Notes:

[216] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|-----------------------------------|
| Statistical analysis title | Statistical analysis 41 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |

| | |
|---|--------------------------|
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[217] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 9.82 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.47 |
| upper limit | 17.64 |

Notes:

[217] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 42 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 6 (Menactra-Menveo vs. Naïve)

| | |
|---|-------------------------------------|
| Comparison groups | Naïve Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[218] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 9.55 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.31 |
| upper limit | 17.19 |

Notes:

[218] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|-----------------------------------|-------------------------|
| Statistical analysis title | Statistical analysis 43 |
|-----------------------------------|-------------------------|

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

| | |
|---|--|
| Comparison groups | Naïve Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[219] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 9.69 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.59 |
| upper limit | 16.79 |

Notes:

[219] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|---|
| Statistical analysis title | Statistical analysis 44 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[220] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.03 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.69 |
| upper limit | 1.54 |

Notes:

[220] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-----------------------------------|
| Statistical analysis title | Statistical analysis 45 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive) | |
| Comparison groups | Menveo-Menveo Group v Naive Group |
| Number of subjects included in analysis | 383 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[221] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 28.52 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 20.23 |
| upper limit | 40.2 |

Notes:

[221] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|-------------------------------------|
| Statistical analysis title | Statistical analysis 46 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive) | |
| Comparison groups | Naive Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 375 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[222] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 26.94 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.09 |
| upper limit | 38.02 |

Notes:

[222] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|---|--|
| Statistical analysis title | Statistical analysis 47 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve) | |
| Comparison groups | Naive Group v pooled group (menveo-menveo and menactra-menveo) |
| Number of subjects included in analysis | 665 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[223] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 27.73 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 20.1 |
| upper limit | 38.26 |

Notes:

[223] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

| | |
|--|---|
| Statistical analysis title | Statistical analysis 48 |
| Statistical analysis description: | |
| Serogroup Y-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo) | |
| Comparison groups | Menveo-Menveo Group v Menactra-Menveo Group |
| Number of subjects included in analysis | 572 |
| Analysis specification | Pre-specified |
| Analysis type | other ^[224] |
| Parameter estimate | Between group GMT ratios |
| Point estimate | 1.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.35 |

Notes:

[224] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Secondary: Within group hSBA Geometric Mean Ratios (GMRs)

| | |
|--|--|
| End point title | Within group hSBA Geometric Mean Ratios (GMRs) |
| End point description: | |
| Within each study group and for each serogroup, GMRs were calculated, at: Visit Day 4 versus at Visit Day 1; Visit Day 6 versus at Visit Day 1; and Visit Day 29 versus at Visit Day 1. The unadjusted GMRs and 95% CIs are constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs. | |
| End point type | Secondary |
| End point timeframe: | |
| At Day 4, Day 6, Day 29 compared to Day 1 | |

| End point values | Menveo- Menveo Group | Menactra- Menveo Group | Naive Group | pooled group (menveo- menveo and menactra- menveo) |
|--|-----------------------------|-----------------------------|---------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 289 | 282 | 93 | 571 |
| Units: Ratios | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-Men A, Day 4/Day 1(N- 144,138,48,282) | 1.02 (0.93 to 1.12) | 1.07 (0.97 to 1.17) | 0.99 (0.84 to 1.16) | 1.04 (0.98 to 1.11) |
| hSBA-Men A, Day 6/Day 1(N- 145,140,44,285) | 4.58 (3.49 to 6) | 3.25 (2.46 to 4.28) | 1.09 (0.66 to 1.78) | 3.87 (3.19 to 4.7) |
| hSBA-Men A, Day 29/Day 1(N- 289,282,93,571) | 75.02 (63.87 to 88.12) | 80.13 (68.09 to 94.3) | 14.14 (10.65 to 18.77) | 77.5 (69.12 to 86.9) |
| hSBA-Men C, Day 4/Day 1(N- 143,137,48,280) | 1.12 (0.99 to 1.28) | 1.35 (1.19 to 1.54) | 1.21 (0.97 to 1.51) | 1.23 (1.12 to 1.35) |
| hSBA-Men C, Day 6/Day 1(N- 144,139,44,283) | 7.25 (5.39 to 9.75) | 7.94 (5.87 to 10.73) | 1.45 (0.85 to 2.48) | 7.58 (6.14 to 9.36) |
| hSBA-Men C, Day 29/Day 1(N- 288,280,93,568) | 71.72 (58.88 to 87.37) | 97.13 (79.51 to 118.65) | 11.81 (8.34 to 16.71) | 83.29 (72.34 to 95.89) |
| hSBA-Men W, Day 4/Day 1(N- 144,138,48,282) | 1.05 (0.91 to 1.23) | 1.4 (1.2 to 1.63) | 1.14 (0.88 to 1.48) | 1.21 (1.09 to 1.35) |
| hSBA-Men W, Day 6/Day 1(N- 145,140,44,285) | 5.71 (4.37 to 7.45) | 6.27 (4.78 to 8.23) | 1.32 (0.81 to 2.15) | 5.98 (4.95 to 7.23) |
| hSBA-Men W, Day 29/Day 1(N- 289,281,92,570) | 63.63 (51.37 to 78.81) | 80.61 (64.88 to 100.14) | 4.57 (3.13 to 6.68) | 71.5 (61.38 to 83.27) |
| hSBA-Men Y, Day 4/Day 1(N- 142,137,48,279) | 1.35 (1.15 to 1.59) | 1.31 (1.11 to 1.54) | 0.99 (0.75 to 1.31) | 1.33 (1.19 to 1.49) |
| hSBA-Men Y, Day 6/Day 1(N- 143,140,44,283) | 6.09 (4.53 to 8.19) | 8.59 (6.37 to 11.59) | 1.48 (0.87 to 2.52) | 7.22 (5.85 to 8.92) |
| hSBA-Men Y, Day 29/Day 1(N- 287,280,93,567) | 116.58 (94.42 to 143.95) | 123.41 (99.69 to 152.78) | 8.21 (5.67 to 11.89) | 119.91 (103.21 to 139.3) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were assessed between 6 hours through Day 7. Unsolicited AEs were assessed between Day 1 through Day 29. SAEs were assessed during the entire study period (From Day 1 to Day 181)

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | Menveo-Menveo Group |
|-----------------------|---------------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| | |
|-----------------------|-------------|
| Reporting group title | Naive Group |
|-----------------------|-------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.

| | |
|-----------------------|-----------------------|
| Reporting group title | Menactra-Menveo Group |
|-----------------------|-----------------------|

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

| Serious adverse events | Menveo-Menveo Group | Naive Group | Menactra-Menveo Group |
|---|---------------------|-----------------|-----------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 301 (1.00%) | 3 / 100 (3.00%) | 2 / 300 (0.67%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Intentional overdose | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |
| Nervous system disorders | | | |
| Diabetic ketoacidotic hyperglycaemic coma | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Abortion spontaneous subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Respiratory disorder subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |
| Psychiatric disorders | | | |
| Suicide attempt subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Major depression subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |
| Suicidal ideation subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Diverticulitis subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (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 |
| Septic shock | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (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 |

Frequency threshold for reporting non-serious adverse events: 0 %

| Non-serious adverse events | Menveo-Menveo Group | Naive Group | Menactra-Menveo Group |
|--|---------------------|-------------------|-----------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 243 / 301 (80.73%) | 60 / 100 (60.00%) | 211 / 300 (70.33%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign bone neoplasm | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin papilloma | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Vascular disorders | | | |
| Lymphangiopathy | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hot flush | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Essential hypertension | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Injection site pain | | | |
| subjects affected / exposed | 119 / 301 (39.53%) | 41 / 100 (41.00%) | 106 / 300 (35.33%) |
| occurrences (all) | 124 | 41 | 113 |
| Fatigue | | | |

| | | | |
|------------------------------|--------------------|-------------------|--------------------|
| subjects affected / exposed | 116 / 301 (38.54%) | 19 / 100 (19.00%) | 111 / 300 (37.00%) |
| occurrences (all) | 146 | 21 | 159 |
| Chills | | | |
| subjects affected / exposed | 34 / 301 (11.30%) | 10 / 100 (10.00%) | 37 / 300 (12.33%) |
| occurrences (all) | 36 | 10 | 50 |
| Injection site induration | | | |
| subjects affected / exposed | 17 / 301 (5.65%) | 8 / 100 (8.00%) | 10 / 300 (3.33%) |
| occurrences (all) | 17 | 9 | 11 |
| Injection site erythema | | | |
| subjects affected / exposed | 14 / 301 (4.65%) | 11 / 100 (11.00%) | 10 / 300 (3.33%) |
| occurrences (all) | 16 | 14 | 10 |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 301 (1.00%) | 1 / 100 (1.00%) | 7 / 300 (2.33%) |
| occurrences (all) | 4 | 1 | 8 |
| Injection site pruritus | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 3 / 100 (3.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 1 | 3 | 2 |
| Influenza like illness | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Chest pain | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Medical device site erythema | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Medical device site swelling | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Peripheral swelling | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Vaccination site pruritus subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Axillary pain subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Injection site bruising subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Hypersensitivity subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Anaphylactic reaction subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Allergy to animal subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Reproductive system and breast disorders Menstruation irregular subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 2 / 300 (0.67%) 2 |
| Metrorrhagia subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Pelvic congestion | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 7 / 301 (2.33%) | 1 / 100 (1.00%) | 5 / 300 (1.67%) |
| occurrences (all) | 7 | 1 | 5 |
| Asthma | | | |
| subjects affected / exposed | 7 / 301 (2.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 7 | 0 | 1 |
| Nasal congestion | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 1 / 100 (1.00%) | 6 / 300 (2.00%) |
| occurrences (all) | 2 | 1 | 6 |
| Cough | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 6 / 300 (2.00%) |
| occurrences (all) | 2 | 0 | 6 |
| Epistaxis | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 2 | 0 | 2 |
| Wheezing | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Sinus congestion | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 100 (1.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 1 | 1 | 2 |
| Rhinitis allergic | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 1 | 0 | 2 |
| Snoring | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dysphonia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Dyspnoea | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary congestion | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Rhonchi | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 5 / 301 (1.66%) | 0 / 100 (0.00%) | 3 / 300 (1.00%) |
| occurrences (all) | 5 | 0 | 3 |
| Depression | | | |
| subjects affected / exposed | 4 / 301 (1.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 4 | 0 | 1 |
| Attention deficit/hyperactivity disorder | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 2 | 0 | 2 |
| Major depression | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Sleep disorder | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Disruptive mood dysregulation disorder | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Post-traumatic stress disorder subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Investigations Cardiac murmur subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Laceration subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Ligament sprain subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 0 / 100 (0.00%) 0 | 3 / 300 (1.00%) 3 |
| Arthropod bite subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Concussion subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 0 / 100 (0.00%) 0 | 2 / 300 (0.67%) 2 |
| Procedural pain subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 1 / 100 (1.00%) 1 | 1 / 300 (0.33%) 1 |
| Limb injury subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Meniscus injury subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 2 / 300 (0.67%) 2 |
| Joint injury | | | |

| | | | |
|------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Arthropod sting | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ligament rupture | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Post procedural complication | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hand fracture | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Alcohol poisoning | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Conjunctival abrasion | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Facial bones fracture | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Joint dislocation | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Muscle strain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pulmonary contusion | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Foot fracture | | | |

| | | | |
|--|---------------------------|-------------------------|--------------------------|
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Cardiac disorders | | | |
| Angina pectoris | | | |
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed occurrences (all) | 103 / 301 (34.22%) 135 | 23 / 100 (23.00%) 27 | 84 / 300 (28.00%) 118 |
| Syncope | | | |
| subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 0 / 100 (0.00%) 0 | 3 / 300 (1.00%) 3 |
| Migraine | | | |
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Loss of consciousness | | | |
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Migraine with aura | | | |
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Tension headache | | | |
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Dizziness | | | |
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 4 / 300 (1.33%) 4 |
| Presyncope | | | |
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed occurrences (all) | 1 / 301 (0.33%) 1 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Anaemia | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 0 / 100 (0.00%) 0 | 2 / 300 (0.67%) 2 |
| Ear and labyrinth disorders | | | |
| Ear pain | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tympanic membrane perforation | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cerumen impaction | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Middle ear effusion | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Vertigo | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |
| Oculogyric crisis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Retinal tear | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Conjunctivitis allergic | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorder | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Vision blurred | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema of eyelid | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed occurrences (all) | 0 / 301 (0.00%) 0 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 51 / 301 (16.94%) | 15 / 100 (15.00%) | 44 / 300 (14.67%) |
| occurrences (all) | 65 | 17 | 55 |
| Abdominal pain | | | |
| subjects affected / exposed | 5 / 301 (1.66%) | 1 / 100 (1.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 5 | 1 | 1 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 3 / 300 (1.00%) |
| occurrences (all) | 2 | 0 | 3 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 3 / 100 (3.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 2 | 3 | 2 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 2 | 0 | 1 |
| Tooth impacted | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Haemorrhoids | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Abdominal tenderness | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Food poisoning | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 0 | 0 | 2 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|--|-----------------|-----------------|-----------------|
| Anal skin tags | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Constipation | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Eosinophilic oesophagitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Salivary gland mucocoele | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Umbilical hernia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Hepatobiliary disorders | | | |
| Biliary dyskinesia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis contact | | | |
| subjects affected / exposed | 4 / 301 (1.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 4 | 0 | 1 |
| Acne | | | |
| subjects affected / exposed | 3 / 301 (1.00%) | 0 / 100 (0.00%) | 5 / 300 (1.67%) |
| occurrences (all) | 3 | 0 | 5 |
| Rash | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 0 | 2 |
| Alopecia | | | |

| | | | |
|---|-------------------|-------------------|-------------------|
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Ecchymosis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Renal and urinary disorders | | | |
| Haematuria | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 2 | 0 | 1 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pollakiuria | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Polyuria | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Proteinuria | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed | 57 / 301 (18.94%) | 15 / 100 (15.00%) | 55 / 300 (18.33%) |
| occurrences (all) | 63 | 15 | 72 |
| Arthralgia | | | |
| subjects affected / exposed | 46 / 301 (15.28%) | 13 / 100 (13.00%) | 41 / 300 (13.67%) |
| occurrences (all) | 60 | 13 | 50 |
| Pain in extremity | | | |

| | | | |
|-----------------------------|------------------|-----------------|-----------------|
| subjects affected / exposed | 4 / 301 (1.33%) | 1 / 100 (1.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 4 | 2 | 1 |
| Back pain | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Metatarsalgia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Myalgia intercostal | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rheumatoid arthritis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Synovial cyst | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Joint stiffness | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Groin pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Muscle tightness | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 13 / 301 (4.32%) | 2 / 100 (2.00%) | 5 / 300 (1.67%) |
| occurrences (all) | 16 | 2 | 5 |

| | | | |
|---|------------------------|----------------------|----------------------|
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 12 / 301 (3.99%) 12 | 3 / 100 (3.00%) 3 | 9 / 300 (3.00%) 9 |
| Acute sinusitis subjects affected / exposed occurrences (all) | 11 / 301 (3.65%) 13 | 1 / 100 (1.00%) 1 | 0 / 300 (0.00%) 0 |
| Otitis media subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 0 / 100 (0.00%) 0 | 4 / 300 (1.33%) 4 |
| Bronchitis subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 1 / 100 (1.00%) 1 | 3 / 300 (1.00%) 3 |
| Pneumonia mycoplasmal subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Cellulitis subjects affected / exposed occurrences (all) | 4 / 301 (1.33%) 4 | 0 / 100 (0.00%) 0 | 0 / 300 (0.00%) 0 |
| Influenza subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 3 / 100 (3.00%) 3 | 7 / 300 (2.33%) 7 |
| Pharyngitis subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 1 / 100 (1.00%) 1 | 5 / 300 (1.67%) 5 |
| Pharyngitis streptococcal subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 0 / 100 (0.00%) 0 | 3 / 300 (1.00%) 3 |
| Viral pharyngitis subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 4 | 0 / 100 (0.00%) 0 | 2 / 300 (0.67%) 2 |
| Otitis media acute subjects affected / exposed occurrences (all) | 3 / 301 (1.00%) 3 | 0 / 100 (0.00%) 0 | 1 / 300 (0.33%) 1 |
| Sinusitis subjects affected / exposed occurrences (all) | 2 / 301 (0.66%) 2 | 1 / 100 (1.00%) 1 | 6 / 300 (2.00%) 7 |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 2 / 100 (2.00%) | 3 / 300 (1.00%) |
| occurrences (all) | 2 | 4 | 3 |
| Conjunctivitis | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 2 | 0 | 1 |
| Otitis externa | | | |
| subjects affected / exposed | 2 / 301 (0.66%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 2 | 0 | 1 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 6 / 300 (2.00%) |
| occurrences (all) | 1 | 0 | 6 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 1 | 0 | 2 |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 100 (1.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 1 | 1 | 1 |
| Folliculitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bronchitis viral | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Croup infectious | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Cystitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Pneumonia bacterial | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral rash | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 2 / 300 (0.67%) |
| occurrences (all) | 0 | 0 | 3 |
| Bacterial vaginosis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 1 | 1 |
| Bartholin's abscess | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Chlamydial infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Fungal infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|------------------------------------|-------------------|-----------------|-------------------|
| Rhinitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Kidney infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vaginal infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 100 (1.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 37 / 301 (12.29%) | 6 / 100 (6.00%) | 48 / 300 (16.00%) |
| occurrences (all) | 50 | 6 | 63 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vitamin D deficiency | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 100 (0.00%) | 0 / 300 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Dehydration | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 100 (0.00%) | 1 / 300 (0.33%) |
| occurrences (all) | 0 | 0 | 1 |

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