



Clinical trial results:

A phase II, open, multi-center study to evaluate the long-term anti-body persistence at 1 year, 3 years and 5 years after the administration of one or two doses of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate (MenACWY-TT) vaccine in healthy toddlers at 9-12 months of age, and to evaluate the safety and immunogenicity of a booster dose of MenACWY-TT administered 5 years post-primary vaccination and of a primary vaccination of MenACWY-TT in a newly enrolled group, aged 5-6 years, as a naïve control.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-002719-24 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 28 March 2014 |

Results information

| | |
|--------------------------------|---|
| Result version number | v3 (current) |
| This version publication date | 31 March 2023 |
| First version publication date | 02 July 2015 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Correction of full data set and alignment between registries. |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | 112021 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00718666 |
| 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, 044 2089-904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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 | 15 October 2014 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 13 November 2013 |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 March 2014 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the long-term persistence of the immunogenicity induced by one or two doses of MenACWY-TT vaccine administered at 12 months or 9 and 12 months of age in terms of the percentage of subjects with *N. meningitidis* serogroup A (MenA), *N. meningitidis* serogroup C (MenC), *N. meningitidis* serogroup W-135 (MenW-135), and *N. meningitidis* serogroup Y (MenY) antibody titers $\geq 1:8$ as measured by a serum bactericidal assay using human complement (hSBA).

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination/product administration with appropriate medical treatment readily available. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed-up for 30 days after the last vaccination/product administration.

Background therapy: -

Evidence for comparator: -

| | |
|---|-----------------|
| Actual start date of recruitment | 20 October 2008 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 5 Years |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United States: 387 |
| Worldwide total number of subjects | 387 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|-----|
| wk | |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 387 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Not all study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Pre-assignment

Screening details:

Out of 387 subjects originally enrolled in the study, only 248 subjects received vaccination.

Period 1

| | |
|------------------------------|--------------------------|
| Period 1 title | Persistence Phase Year 1 |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|---------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nimenrix 1 Group Y1 |

Arm description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| | |
|------------------|---------------------|
| Arm title | Nimenrix 2 Group Y1 |
|------------------|---------------------|

Arm description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| Number of subjects in period 1 ^[1] | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 |
|--|---------------------|---------------------|
| Started | 118 | 130 |
| Completed | 118 | 130 |

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: Not all study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Period 2

| | |
|------------------------------|--------------------------|
| Period 2 title | Persistence Phase Year 3 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|---------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nimenrix 1 Group Y3 |

Arm description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| | |
|------------------|---------------------|
| Arm title | Nimenrix 2 Group Y3 |
|------------------|---------------------|

Arm description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| Number of subjects in period 2 ^[2] | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 |
|---|---------------------|---------------------|
| | | |
| Started | 98 | 104 |
| Completed | 98 | 104 |

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Period 3

| | |
|------------------------------|--------------------------|
| Period 3 title | Persistence Phase Year 5 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|---------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nimenrix 1 Group Y5 |

Arm description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| | |
|------------------|---------------------|
| Arm title | Nimenrix 2 Group Y5 |
|------------------|---------------------|

Arm description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| Number of subjects in period 3 ^[3] | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 |
|--|---------------------|---------------------|
| | | |
| Started | 70 | 82 |
| Completed | 70 | 82 |

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Period 4

| | |
|------------------------------|-------------------------|
| Period 4 title | Booster Phase Year 5 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nimenrix 1 Booster Group |

Arm description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| | |
|--|-------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| | |
|------------------|--------------------------|
| Arm title | Nimenrix 2 Booster Group |
|------------------|--------------------------|

Arm description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| | |
|------------------|----------------------|
| Arm title | Nimenrix Naive Group |
|------------------|----------------------|

Arm description:

Vaccine-naïve subjects aged 5-6 years were enrolled to receive Nimenrix vaccine as primary vaccination at Year 5.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|-------------------|
| Investigational medicinal product name | Nimenrix |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One intramuscular injection in the deltoid of non-dominant arm.

| Number of subjects in period 4 | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group |
|--|---------------------------------|---------------------------------|-----------------------------|
| Started | 38 | 46 | 68 |
| Completed | 36 | 46 | 94 |
| Not completed | 2 | 0 | 6 |
| Consent withdrawn by subject | - | - | 1 |
| No active participation request | - | - | 1 |
| Lost to follow-up | 1 | - | 4 |
| Declined v-4 serology | 1 | - | - |
| Joined | 0 | 0 | 32 |
| Harmonization of subject numbers between periods | - | - | 32 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------------|
| Reporting group title | Nimenrix 1 Group Y1 |
|-----------------------|---------------------|

Reporting group description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| | |
|-----------------------|---------------------|
| Reporting group title | Nimenrix 2 Group Y1 |
|-----------------------|---------------------|

Reporting group description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| Reporting group values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | Total |
|--|---------------------|---------------------|-------|
| Number of subjects | 118 | 130 | 248 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | 0 |
| Preterm newborn infants (gestational age < 37 wks) | | | 0 |
| Newborns (0-27 days) | | | 0 |
| Infants and toddlers (28 days-23 months) | | | 0 |
| Children (2-11 years) | | | 0 |
| Adolescents (12-17 years) | | | 0 |
| Adults (18-64 years) | | | 0 |
| From 65-84 years | | | 0 |
| 85 years and over | | | 0 |
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 24.5 | 24.6 | |
| standard deviation | ± 0.97 | ± 1 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 56 | 66 | 122 |
| Male | 62 | 64 | 126 |

End points

End points reporting groups

| | |
|---|--------------------------|
| Reporting group title | Nimenrix 1 Group Y1 |
| Reporting group description: Subjects who received 1 dose of Nimenrix vaccine at 12 months of age. | |
| Reporting group title | Nimenrix 2 Group Y1 |
| Reporting group description: Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age. | |
| Reporting group title | Nimenrix 1 Group Y3 |
| Reporting group description: Subjects who received 1 dose of Nimenrix vaccine at 12 months of age. | |
| Reporting group title | Nimenrix 2 Group Y3 |
| Reporting group description: Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age. | |
| Reporting group title | Nimenrix 1 Group Y5 |
| Reporting group description: Subjects who received 1 dose of Nimenrix vaccine at 12 months of age. | |
| Reporting group title | Nimenrix 2 Group Y5 |
| Reporting group description: Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age. | |
| Reporting group title | Nimenrix 1 Booster Group |
| Reporting group description: Subjects who received 1 dose of Nimenrix vaccine at 12 months of age. | |
| Reporting group title | Nimenrix 2 Booster Group |
| Reporting group description: Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age. | |
| Reporting group title | Nimenrix Naive Group |
| Reporting group description: Vaccine-naive subjects aged 5-6 years were enrolled to receive Nimenrix vaccine as primary vaccination at Year 5. | |

Primary: Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers equal to or above the cut-off values

| | |
|---|---|
| End point title | Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers equal to or above the cut-off values ^[1] |
| End point description: hSBA antibody titers were assessed for the MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was equal to or above (\geq) 1:8. | |
| End point type | Primary |
| End point timeframe: At Year 1 (12 months post primary vaccination) | |

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 110 | 120 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M12, $\geq 1:8$ (N=102; 108) | 21 | 28 | | |
| hSBA-MenC, M12 $\geq 1:8$ (N=104; 113) | 91 | 103 | | |
| hSBA-MenW-135, M12 $\geq 1:8$ (N=104; 112) | 93 | 111 | | |
| hSBA-MenY, M12 $\geq 1:8$ (N=110; 120) | 88 | 111 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers \geq the cut-off value

| | |
|-----------------|---|
| End point title | Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers \geq the cut-off value ^[2] |
|-----------------|---|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:8$.

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

End point timeframe:

At Year 3 (36 months post primary vaccination)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 86 | 97 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M36, $\geq 1:8$ (N=82; 96) | 14 | 16 | | |
| hSBA-MenC, M36 $\geq 1:8$ (N=81; 94) | 57 | 68 | | |
| hSBA-MenW-135, M36 $\geq 1:8$ (N=86; 97) | 54 | 82 | | |
| hSBA-MenY, M36 $\geq 1:8$ (N=85; 95) | 53 | 59 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers \geq the cut-off value

| | |
|-----------------|---|
| End point title | Number of subjects with serum bactericidal assay (using human complement) (hSBA) titers \geq the cut-off value ^[3] |
|-----------------|---|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:8$.

End point type Primary

End point timeframe:

At Year 5 (60 months post primary vaccination)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 63 | 72 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M60, $\geq 1:8$ (N=63; 71) | 20 | 27 | | |
| hSBA-MenC, M60 $\geq 1:8$ (N=60; 71) | 45 | 53 | | |
| hSBA-MenW-135, M60 $\geq 1:8$ (N=61; 72) | 40 | 62 | | |
| hSBA-MenY, M60 $\geq 1:8$ (N=50; 63) | 32 | 49 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value

End point title Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:4$.

End point type Secondary

End point timeframe:

At Year 1 (12 months post vaccination)

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 110 | 120 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M12, $\geq 1:4$ (N=102; 108) | 23 | 29 | | |
| hSBA-MenC, M12 $\geq 1:4$ (N=104; 113) | 91 | 103 | | |
| hSBA-MenW-135, M12 $\geq 1:4$ (N=104; 112) | 93 | 111 | | |
| hSBA-MenY, M12 $\geq 1:4$ (N=110; 120) | 89 | 111 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value

| | |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value |
|-----------------|--|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:4$.

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

End point timeframe:

At Year 3 (36 months post primary vaccination)

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 86 | 97 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M36, $\geq 1:4$ (N=82; 96) | 14 | 19 | | |
| hSBA-MenC, M36 $\geq 1:4$ (N=81; 94) | 59 | 69 | | |
| hSBA-MenW-135, M36 $\geq 1:4$ (N=86; 97) | 54 | 82 | | |
| hSBA-MenY, M36 $\geq 1:4$ (N=85; 95) | 53 | 59 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value

| | |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY titers \geq the cut-off value |
|-----------------|--|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:4$.

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

End point timeframe:

At Year 5 (60 months post primary vaccination)

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 63 | 72 | | |
| Units: Subjects | | | | |
| hSBA-MenA, M60, $\geq 1:4$ (N=63; 71) | 20 | 27 | | |
| hSBA-MenC, M60 $\geq 1:4$ (N=60; 71) | 47 | 56 | | |
| hSBA-MenW-135, M60 $\geq 1:4$ (N=61; 72) | 40 | 62 | | |
| hSBA-MenY, M60 $\geq 1:4$ (N=50; 63) | 32 | 49 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers

| | |
|---|--|
| End point title | hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers |
| End point description: Titers are given as geometric mean titers (GMTs) for the serogroups hSBA-MenA, hSBA-MenC, hSBAMenW-135, and hSBA-MenY respectively, calculated on all subjects. | |
| End point type | Secondary |
| End point timeframe: At Year 1 (12 months post primary vaccination) | |

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 110 | 120 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA, M12 (N=102; 108) | 3.7 (2.9 to 4.8) | 4.1 (3.2 to 5.2) | | |
| hSBA-MenC, M12 (N=104; 113) | 70.5 (50.4 to 98.5) | 72.4 (53.3 to 98.4) | | |
| hSBA-MenW-135, M12 (N=104; 112) | 127.9 (87.3 to 187.3) | 204.6 (163.6 to 255.9) | | |
| hSBA-MenY, M12 (N=110; 120) | 55.6 (38.1 to 81.1) | 86.2 (65.8 to 112.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers

| | |
|-----------------|--|
| End point title | hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers |
|-----------------|--|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups hSBA-MenA, hSBA-MenC, hSBAMenW-135, and hSBA-MenY respectively, calculated on all subjects.

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

End point timeframe:

At Year 3 (36 months post primary vaccination)

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 86 | 97 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA, M36 (N=82; 96) | 3.5 (2.6 to 4.6) | 3.4 (2.7 to 4.3) | | |
| hSBA-MenC, M36 (N=81; 94) | 31.2 (18.9 to 51.6) | 29.8 (18.9 to 47) | | |
| hSBA-MenW-135, M36 (N=86; 97) | 29 (18 to 46.9) | 63.9 (44 to 92.8) | | |
| hSBA-MenY, M36 (N=85; 95) | 22 (14 to 34.5) | 20.5 (13.6 to 30.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers

| | |
|-----------------|--|
| End point title | hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY antibody titers |
|-----------------|--|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups hSBA-MenA, hSBA-MenC, hSBAMenW-135, and hSBA-MenY respectively, calculated on all subjects.

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

End point timeframe:

At Year 5 (60 months post primary vaccination)

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 63 | 72 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA, M60 (N=63; 71) | 4.6 (3.3 to 6.3) | 6.6 (4.5 to 9.8) | | |
| hSBA-MenC, M60 (N=60; 71) | 40.7 (22.7 to 73.1) | 38.2 (22.5 to 64.9) | | |
| hSBA-MenW-135, M60 (N=61; 72) | 24.2 (14.4 to 40.7) | 53.7 (35.8 to 80.4) | | |
| hSBA-MenY, M60 (N=50; 63) | 26 (14.1 to 47.8) | 37.9 (24.3 to 59.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay

| | |
|-----------------|--|
| End point title | Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay |
|-----------------|--|

End point description:

rSBA antibody titers were assessed for the rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:8$ and $1:128$. The analysis was performed by GSK Biologicals' laboratory assay.

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

End point timeframe:

At Year 1 (12 months post primary vaccination)

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 101 | 114 | | |
| Units: Subjects | | | | |
| rSBA-MenA, M12 $\geq 1:8$ (N=95; 104) | 90 | 101 | | |
| rSBA-MenA, M12 $\geq 1:128$ (N=95; 104) | 71 | 80 | | |
| rSBA-MenC, M12 $\geq 1:8$ (N=95; 112) | 83 | 96 | | |
| rSBA-MenC, M12 $\geq 1:128$ (N=95; 112) | 46 | 54 | | |
| rSBA-MenW-135, M12 $\geq 1:8$ (N=101;114) | 97 | 114 | | |
| rSBA-MenW-135, M12 $\geq 1:128$ (N=101;114) | 82 | 89 | | |
| rSBA-MenY, M12 $\geq 1:8$ (N=101; 113) | 96 | 113 | | |
| rSBA-MenY, M12 $\geq 1:128$ (N=101; 113) | 85 | 100 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay

| | |
|-----------------|--|
| End point title | Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay |
|-----------------|--|

End point description:

rSBA antibody titers were assessed for the rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:8$ and $1:128$. The analysis was performed by GSK Biologicals' laboratory assay.

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

End point timeframe:

At Year 3 (36 months post primary vaccination)

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 73 | 89 | | |
| Units: Subjects | | | | |
| rSBA-MenA, M12 $\geq 1:8$ (N=69;84) | 65 | 82 | | |
| rSBA-MenA, M12 $\geq 1:128$ (N=69;84) | 51 | 65 | | |
| rSBA-MenC, M12 $\geq 1:8$ (N=68;89) | 60 | 75 | | |
| rSBA-MenC, M12 $\geq 1:128$ (N=68;89) | 32 | 40 | | |
| rSBA-MenW-135, M12 $\geq 1:8$ (N=72;88) | 68 | 88 | | |
| rSBA-MenW-135, M12 $\geq 1:128$ (N=72;88) | 56 | 69 | | |
| rSBA-MenY, M12 $\geq 1:8$ (N=73;89) | 69 | 89 | | |
| rSBA-MenY, M12 $\geq 1:128$ (N=73;89) | 62 | 78 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|-----------------|----------------------|
| End point title | rSBA antibody titers |
|-----------------|----------------------|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups rSBA-MenA, rSBA-MenC, rSBAMenW-135, and rSBA-MenY respectively, as performed by GSK Biologicals' laboratory assay.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Year 1 (12 months post primary vaccination) | |

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 101 | 114 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, M12 (N=95; 104) | 259.7 (191.4 to 352.3) | 237.2 (187 to 301) | | |
| rSBA-MenC, M12 (N=95; 112) | 94.1 (67.1 to 131.9) | 90.3 (65.5 to 124.4) | | |
| rSBA-MenW-135, M12 (N=101; 114) | 385.2 (286.4 to 518.1) | 345.3 (280.1 to 425.8) | | |
| rSBA-MenY, M12 (N=101; 113) | 364.5 (273.7 to 485.4) | 342.2 (284.5 to 411.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|--|----------------------|
| End point title | rSBA antibody titers |
| End point description: | |
| Titers are given as geometric mean titers (GMTs) for the serogroups rSBA-MenA, rSBA-MenC, rSBAMenW-135, and rSBA-MenY respectively, as performed by GSK Biologicals' laboratory assay. | |
| End point type | Secondary |
| End point timeframe: | |
| At Year 3 (36 months post-primary vaccination) | |

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 73 | 89 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, M12 (N=69; 84) | 247.9 (173.8 to 353.7) | 241.8 (185.6 to 315) | | |
| rSBA-MenC, M12 (N=68; 89) | 87 (59.3 to 127.8) | 76.4 (53.5 to 109) | | |
| rSBA-MenW-135, M12 (N=72; 88) | 353.3 (240 to 520.1) | 358 (282.8 to 453.3) | | |
| rSBA-MenY, M12 (N=73; 89) | 360.5 (253.4 to 512.9) | 341.4 (276.9 to 421.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay

| | |
|-----------------|--|
| End point title | Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay |
|-----------------|--|

End point description:

rSBA antibody titers were assessed for the rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY serogroups respectively. The antibody cut-off value assessed was $\geq 1:8$ and $1:128$ Titers were determined by Public Health England (PHE) laboratory assay.

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

End point timeframe:

At Year 3 (36 months post primary vaccination)

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 98 | | |
| Units: Subjects | | | | |
| rSBA-MenA, M36, $\geq 1:8$ (N=83; 97) | 38 | 44 | | |
| rSBA-MenA, M36, $\geq 1:128$ (N=83; 97) | 23 | 24 | | |
| rSBA-MenC, M36, $\geq 1:8$ (N=83; 97) | 27 | 30 | | |
| rSBA-MenC, M36, $\geq 1:128$ (N=83; 97) | 18 | 15 | | |
| rSBA-MenW-135, M36, $\geq 1:8$ (N=83; 95) | 36 | 35 | | |
| rSBA-MenW-135, M36, $\geq 1:128$ (N=83; 95) | 24 | 23 | | |
| rSBA-MenY, M36, $\geq 1:8$ (N=83; 98) | 39 | 45 | | |
| rSBA-MenY, M36, $\geq 1:128$ (N=83; 98) | 21 | 24 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|-----------------|----------------------|
| End point title | rSBA antibody titers |
|-----------------|----------------------|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY respectively. Titers were determined by Public Health England (PHE)

laboratory assay.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Year 3 (36 months following primary vaccination) | |

| End point values | Nimenrix 1 Group Y3 | Nimenrix 2 Group Y3 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 83 | 98 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, M36 (N=83; 97) | 18.4 (12 to 28.3) | 16.6 (11.3 to 24.3) | | |
| rSBA-MenC, M36 (N=83; 97) | 13.2 (8.6 to 20.2) | 10.6 (7.4 to 15) | | |
| rSBA-MenW-135, M36 (N=83; 95) | 19.4 (12.3 to 30.6) | 14.6 (9.7 to 21.8) | | |
| rSBA-MenY, M36 (N=83; 98) | 19.6 (12.7 to 30.1) | 16.7 (11.5 to 24.3) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody to Polysaccharide N. meningitidis Serogroup A, C, W-135 and Y (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) antibody concentrations

| | |
|-----------------|--|
| End point title | Antibody to Polysaccharide N. meningitidis Serogroup A, C, W-135 and Y (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) antibody concentrations |
|-----------------|--|

End point description:

Results were tabulated as geometric mean antibody concentration (GMC) calculated on all subjects, expressed in microgram per milliliter (µg/ml).

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Year 1 (12 months post primary vaccination) | |

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 103 | 120 | | |
| Units: µg/ml | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA, M12 (N=103; 120) | 0.45 (0.36 to 0.58) | 0.33 (0.28 to 0.4) | | |
| Anti-PSC, M12 (N=102; 114) | 0.27 (0.22 to 0.32) | 0.25 (0.22 to 0.3) | | |

| | | | | |
|-------------------------------|---------------------|--------------------|--|--|
| Anti-PSW-135, M12 (N=99; 113) | 0.96 (0.74 to 1.25) | 1.2 (1 to 1.44) | | |
| Anti-PSY, M12 (N=98; 117) | 1.41 (1.07 to 1.85) | 1.7 (1.43 to 2.03) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY \geq the cut-off value

| | |
|-----------------|--|
| End point title | Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY \geq the cut-off value |
|-----------------|--|

End point description:

The cut-off values for the assay were 0.3 $\mu\text{g/ml}$ and 2.0 $\mu\text{g/ml}$ respectively.

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

End point timeframe:

At Year 1 (12 months post primary vaccination)

| End point values | Nimenrix 1 Group Y1 | Nimenrix 2 Group Y1 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 103 | 120 | | |
| Units: Subjects | | | | |
| Anti-PSA, M12, $\geq 0.3 \mu\text{g/ml}$ (N=103; 120) | 60 | 59 | | |
| Anti-PSA, M12, $\geq 2.0 \mu\text{g/ml}$ (N=103; 120) | 12 | 6 | | |
| Anti-PSC, M12, $\geq 0.3 \mu\text{g/ml}$ (N=102; 114) | 36 | 39 | | |
| Anti-PSC, M12, $\geq 2.0 \mu\text{g/ml}$ (N=102; 114) | 3 | 4 | | |
| Anti-PSW-135, M12, $\geq 0.3 \mu\text{g/ml}$ (N=99; 113) | 78 | 104 | | |
| Anti-PSW-135, M12, $\geq 2.0 \mu\text{g/ml}$ (N=99; 113) | 28 | 29 | | |
| Anti-PSY, M12, $\geq 0.3 \mu\text{g/ml}$ (N=98; 117) | 84 | 114 | | |
| Anti-PSY, M12, $\geq 2.0 \mu\text{g/ml}$ (N=98; 117) | 45 | 50 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers \geq the cut-off value

| | |
|-----------------|---|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers \geq the cut-off value |
|-----------------|---|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off values assessed were $\geq 1:4$ or $1:8$. This outcome measure only concerns the Nimenrix Naive Group.

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

End point timeframe:

At Month 60 (pre-primary vaccination with Nimenrix vaccine)

| End point values | Nimenrix Naive Group | | | |
|-------------------------------------|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 79 | | | |
| Units: Subjects | | | | |
| hSBA-MenA, PRE(M60), $\geq 1:4$ | 16 | | | |
| hSBA-MenA, PRE(M60), $\geq 1:8$ | 16 | | | |
| hSBA-MenC, PRE(M60), $\geq 1:4$ | 28 | | | |
| hSBA-MenC, PRE(M60), $\geq 1:8$ | 24 | | | |
| hSBA-MenW-135, PRE(M60), $\geq 1:4$ | 28 | | | |
| hSBA-MenW-135, PRE(M60), $\geq 1:8$ | 28 | | | |
| hSBA-MenY, PRE(M60), $\geq 1:4$ | 29 | | | |
| hSBA-MenY, PRE(M60), $\geq 1:8$ | 29 | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers

| | |
|-----------------|--|
| End point title | hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers |
|-----------------|--|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY respectively. This outcome measure only concerns the Nimenrix Naive Group.

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

End point timeframe:

At Month 60 (pre-vaccination with Nimenrix vaccine)

| End point values | Nimenrix Naive Group | | | |
|--|----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 79 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA, PRE(M60) | 3.3 (2.6 to 4.1) | | | |
| hSBA-MenC, PRE(M60) | 5.3 (3.9 to 7.3) | | | |

| | | | | |
|-------------------------|-------------------|--|--|--|
| hSBA-MenW-135, PRE(M60) | 7 (4.7 to 10.4) | | | |
| hSBA-MenY, PRE(M60) | 9.5 (5.9 to 15.1) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers \geq the cut-off value

| | |
|-----------------|---|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers \geq the cut-off value |
|-----------------|---|

End point description:

hSBA antibody titers were assessed for the hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY serogroups respectively. The antibody cut-off values assessed were \geq 1:4 or 1:8.

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

End point timeframe:

At Month 61, one month post-primary vaccination for Nimenrix Naive Group; one month post-booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|---|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 32 | 38 | 79 | |
| Units: Subjects | | | | |
| hSBA-MenA \geq 1:4 (N=31; 38; 79) | 31 | 38 | 62 | |
| hSBA-MenA \geq 1:8 (N=31; 38; 79) | 31 | 38 | 62 | |
| hSBA-MenC \geq 1:4 (N=32; 37; 77) | 32 | 37 | 68 | |
| hSBA-MenC \geq 1:8 (N=32; 37; 77) | 32 | 37 | 66 | |
| hSBA-MenW-135 \geq 1:4 (N=32; 38; 78) | 32 | 38 | 70 | |
| hSBA-MenW-135 \geq 1:8 (N=32; 38; 78) | 32 | 38 | 70 | |
| hSBA-MenY \geq 1:4 (N=32; 38; 70) | 32 | 38 | 66 | |
| hSBA-MenY \geq 1:8 (N=32; 38; 70) | 32 | 38 | 66 | |

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers

| | |
|-----------------|--|
| End point title | hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers |
|-----------------|--|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups hSBA-MenA, hSBA-MenC, hSBA-MenW-135, and hSBA-MenY respectively, calculated on all subjects.

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

End point timeframe:

At Month 61, one month post-primary vaccination for Nimenrix Naive Group; one month post-booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|--|------------------------------|------------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 32 | 38 | 79 | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA (N= 31, 38, 79) | 1395.9 (926.0 to 2104.4) | 1590.1 (1157.4 to 2184.6) | 38.3 (25.4 to 57.9) | |
| hSBA-MenC (N= 32, 37, 77) | 8185.7 (4736.9 to 14145.4) | 12881.2 (8549.1 to 19408.4) | 95.3 (56.5 to 160.9) | |
| hSBA-MenW-135 (N= 32, 38, 78) | 15800.9 (12975.8 to 19241.0) | 20495.9 (16080.2 to 26124.3) | 98.1 (65.8 to 146) | |
| hSBA-MenY (N= 32, 38, 70) | 8809.1 (6926.3 to 11203.9) | 10513.8 (7933.6 to 13933.2) | 198.7 (137.6 to 287) | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine response for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers

| | |
|-----------------|--|
| End point title | Number of subjects with vaccine response for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers |
|-----------------|--|

End point description:

Vaccine response was defines as: for initially seronegative subjects (pre-vaccination titer < 1:4): hSBA post-vaccination antibody titers \geq 1:8 and for seropositive subjects (pre-vaccination titers \geq 1:4): hSBA antibody titers at least four times the pre-vaccination antibody titers.

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

End point timeframe:

At Month 61, one month post-primary vaccination for Nimenrix Naive Group; one month post-booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-------------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 31 | 35 | 77 | |
| Units: Subjects | | | | |
| hSBA-MenA, (N=31; 35; 77) | 31 | 35 | 56 | |
| hSBA-MenC, (N=30; 34; 68) | 28 | 31 | 48 | |
| hSBA-MenW-135, (N=31; 35; 74) | 31 | 35 | 48 | |

| | | | | |
|---------------------------|----|----|----|--|
| hSBA-MenY, (N=26; 31; 61) | 26 | 31 | 48 | |
|---------------------------|----|----|----|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any and grade 3 solicited local symptom

| | |
|-----------------|--|
| End point title | Number of subjects reporting any and grade 3 solicited local symptom |
|-----------------|--|

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain was defined as pain that prevented normal activity. Grade 3 redness/swelling was defined as redness/swelling spreading beyond 50 millimeters (mm) of injection site.

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

End point timeframe:

During the 4-day (Days 0-3) post-primary vaccination for Nimenrix Naive Group and post-booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-----------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 36 | 45 | 89 | |
| Units: Subjects | | | | |
| Any Pain | 18 | 21 | 46 | |
| Any Redness | 10 | 15 | 22 | |
| Any Swelling | 8 | 9 | 21 | |
| Grade 3 Pain | 0 | 1 | 1 | |
| Grade 3 Redness | 1 | 0 | 1 | |
| Grade 3 Swelling | 1 | 0 | 2 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any, grade 3 and related solicited general symptom

| | |
|-----------------|---|
| End point title | Number of subjects reporting any, grade 3 and related solicited general symptom |
|-----------------|---|

End point description:

Assessed solicited general symptoms were fatigue, fever (defined as axillary temperature ≥ 37.5 °C), headache and gastrointestinal. Any was defined as occurrence of the symptom regardless of their intensity grade or relationship to study vaccination. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever higher than (>) 39.5 °C. Related = symptom assessed by the investigator as related to the vaccination.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| During the 4-day (Days 0-3) post-primary vaccination for Nimenrix Naive Group and post-booster for Nimenrix 1 and Nimenrix 2 Groups | |

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-----------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 36 | 45 | 89 | |
| Units: Subjects | | | | |
| Any Fatigue | 10 | 7 | 18 | |
| Grade 3 Fatigue | 0 | 0 | 1 | |
| Related Fatigue | 8 | 6 | 15 | |
| Any Gastrointestinal | 4 | 5 | 7 | |
| Grade 3 Gastrointestinal | 1 | 2 | 0 | |
| Related Gastrointestinal | 3 | 4 | 5 | |
| Any Headache | 4 | 5 | 11 | |
| Grade 3 Headache | 1 | 1 | 1 | |
| Related Headache | 4 | 4 | 8 | |
| Any Fever (Axillary) | 1 | 2 | 5 | |
| Fever (Axillary) >39.5°C | 9 | 0 | 0 | |
| Related Fever (Axillary) | 0 | 1 | 3 | |

Statistical analyses

No statistical analyses for this end point

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 unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. | |
| End point type | Secondary |
| End point timeframe: | |
| During the 31-day (Days 0-30) post-primary vaccination for Nimenrix Naive Group and post-booster for Nimenrix 1 and Nimenrix 2 Groups | |

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-----------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 38 | 46 | 100 | |
| Units: Subjects | | | | |
| Any AE(s) | 9 | 6 | 29 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any serious adverse events (SAEs)

| | |
|-----------------|--|
| End point title | Number of subjects reporting any serious adverse events (SAEs) |
|-----------------|--|

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

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

End point timeframe:

During the 181-day (Days 0-180) post primary vaccination for Nimenrix Naive Group and post booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-----------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 38 | 46 | 100 | |
| Units: Subjects | | | | |
| Any SAE(s) | 0 | 0 | 1 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any new onset of chronic illnesses (NOCIs)

| | |
|-----------------|---|
| End point title | Number of subjects reporting any new onset of chronic illnesses (NOCIs) |
|-----------------|---|

End point description:

NOCIs include autoimmune disorders, asthma, type I diabetes, allergies.

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

End point timeframe:

During the 181-day (Days 0-180) post primary vaccination for Nimenrix Naive Group and post booster for Nimenrix 1 and Nimenrix 2 Groups

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-----------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 38 | 46 | 100 | |
| Units: Subjects | | | | |
| Any NOCI(s) | 0 | 0 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with titers \geq the cut-off, for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay

| | |
|-----------------|---|
| End point title | Number of subjects with titers \geq the cut-off, for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay |
|-----------------|---|

End point description:

rSBA antibody titers were assessed for the rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY serogroups respectively. The antibody cut-off values assessed were $\geq 1:8$ and $1:128$. The analysis was performed by GSK Biologicals' laboratory assay.

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

End point timeframe:

At Year 5 (60 months post-primary vaccination)

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 53 | 64 | | |
| Units: Subjects | | | | |
| rSBA-MenA, M12, $\geq 1:8$ (N=51;59) | 51 | 57 | | |
| rSBA-MenA, M12, $\geq 1:128$ (N=51;59) | 38 | 49 | | |
| rSBA-MenC, M12, $\geq 1:8$ (N=51;63) | 43 | 53 | | |
| rSBA-MenC, M12, $\geq 1:128$ (N=51;63) | 23 | 31 | | |
| rSBA-MenW-135, M12, $\geq 1:8$ (N=52;64) | 51 | 64 | | |
| rSBA-MenW-135, M12, $\geq 1:128$ (N=52;64) | 41 | 53 | | |
| rSBA-MenY, M12, $\geq 1:8$ (N=53;64) | 50 | 64 | | |
| rSBA-MenY, M12, $\geq 1:128$ (N=53;64) | 43 | 58 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|-----------------|----------------------|
| End point title | rSBA antibody titers |
|-----------------|----------------------|

End point description:

Titers are given as geometric mean titers (GMTs), calculated on all subjects for the serogroups rSBA-MenA, rSBA-MenC, rSBAMenW-135, and rSBA-MenY respectively by GSK Biologicals' laboratory assay.

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

End point timeframe:

At Year 5 (60 months post-primary vaccination)

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 53 | 64 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, M12 (N=51;59) | 311.6 (221.8 to 437.6) | 277.5 (200.4 to 384.1) | | |
| rSBA-MenC, M12, (N=51;63) | 88.6 (54.2 to 144.8) | 85.5 (55.1 to 132.5) | | |
| rSBA-MenW-135, M12, (N=52;64) | 339.4 (235.2 to 489.8) | 404.2 (308.5 to 529.7) | | |
| rSBA-MenY, M12, (N=53;64) | 347.6 (223.9 to 539.6) | 367.7 (287.8 to 469.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay

| | |
|-----------------|--|
| End point title | Number of subjects with titers \geq the cut-off for meningococcal polysaccharides A , C, W-135 and Y serum bactericidal antibodies, using baby rabbit complement for assay |
|-----------------|--|

End point description:

rSBA antibody titers were assessed for the rSBA-MenA, rSBA-MenC, rSBA-MenW-135, and rSBA-MenY serogroups respectively. The antibody cut-off value assessed was equal to or above 1:8 and 1:128 by Public Health England [PHE] laboratory assay.

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

End point timeframe:

At Year 5 (60 months post-primary vaccination)

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|---|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 62 | 72 | | |
| Units: Subjects | | | | |
| rSBA-MenA, M60, $\geq 1:8$ (N=61;72) | 38 | 42 | | |
| rSBA-MenA, M60, $\geq 1:128$ (N=61;72) | 22 | 26 | | |
| rSBA-MenC, M60, $\geq 1:8$ (N=62;71) | 29 | 29 | | |
| rSBA-MenC, M60, $\geq 1:128$ (N=62;71) | 16 | 19 | | |
| rSBA-MenW-135, M60, $\geq 1:8$ (N=62;72) | 15 | 22 | | |
| rSBA-MenW-135, M60, $\geq 1:128$ (N=62;72) | 9 | 14 | | |
| rSBA-MenY, M60, $\geq 1:8$ (N=61;72) | 33 | 36 | | |
| rSBA-MenY, M60, $\geq 1:128$ (N=61;72) | 23 | 26 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|--|----------------------|
| End point title | rSBA antibody titers |
| End point description: | |
| Titers are given as geometric mean titers (GMTs), calculated for all subjects for the serogroups rSBA-MenA, rSBA-MenC, rSBAMenW-135, and rSBA-MenY respectively. Titers were determined by Public Health England (PHE) laboratory assay. | |
| End point type | Secondary |
| End point timeframe: | |
| At Year 5 (60 months following primary vaccination) | |

| End point values | Nimenrix 1 Group Y5 | Nimenrix 2 Group Y5 | | |
|--|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 62 | 72 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, M60, (N=61;72) | 32.4 (18.7 to 56) | 32.3 (19.1 to 54.7) | | |
| rSBA-MenC, M60, (N=62;71) | 20 (12 to 33.4) | 16.5 (10.2 to 26.6) | | |
| rSBA-MenW-135, M60, (N=62;72) | 8.9 (5.9 to 13.6) | 11.8 (7.5 to 18.5) | | |
| rSBA-MenY, M60, (N=61;72) | 32 (17.8 to 57.4) | 26.9 (16.2 to 44.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine response with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers

| | |
|-----------------|---|
| End point title | Number of subjects with vaccine response with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers |
|-----------------|---|

End point description:

Vaccine response was defined as: for initially seronegative subjects: antibody titer $\geq 1:32$ at post-vaccination; and for initially seropositive subjects: antibody titer at post-vaccination ≥ 4 fold the pre-vaccination antibody titer. Titers were determined by Public Health England (PHE) laboratory assay.

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

End point timeframe:

At Month 61 (one month post-primary vaccination for Nimenrix Naive Group; one month post-booster for Nimenrix 1 and Nimenrix 2 Groups)

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|-------------------------------|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 30 | 37 | 78 | |
| Units: Subjects | | | | |
| hSBA-MenA, (N=29; 37; 78) | 28 | 36 | 75 | |
| hSBA-MenC, (N=30; 37; 77) | 26 | 32 | 70 | |
| hSBA-MenW-135, (N=30; 37; 78) | 30 | 37 | 77 | |
| hSBA-MenY, (N=29; 37; 78) | 29 | 36 | 78 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq the cut-off values

| | |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq the cut-off values |
|-----------------|--|

End point description:

The cut-off values for the assay were $\geq 1:8$ and $\geq 1:128$. Titers were determined by Public Health England (PHE) laboratory assay.

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

End point timeframe:

At Month 60 and 61 (just prior to and one month post-primary vaccination for Nimenrix Naive Group; one month post-booster vaccination for Nimenrix 1 and Nimenrix 2 Groups)

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|---|-----------------------------|-----------------------------|-------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 31 | 38 | 82 | |
| Units: Subjects | | | | |
| rSBA-MenA, PRE[M60], $\geq 1:8$ (N=30;37;78) | 21 | 23 | 20 | |
| rSBA-MenA, PRE[M60], $\geq 1:128$ (N=30;37;78) | 11 | 14 | 9 | |
| rSBA-MenA, POST[M61], $\geq 1:8$ (N=31;38;81) | 31 | 38 | 81 | |
| rSBA-MenA, POST[M61], $\geq 1:128$ (N=31;38;81) | 31 | 38 | 81 | |
| rSBA-MenC, PRE[M60], $\geq 1:8$ (N=31;37;77) | 15 | 18 | 5 | |
| rSBA-MenC, PRE[M60], $\geq 1:128$ (N=31;37;77) | 6 | 12 | 4 | |
| rSBA-MenC, POST[M61], $\geq 1:8$ (N=31;38;82) | 31 | 38 | 80 | |
| rSBA-MenC, POST[M61], $\geq 1:128$ (N=31;38;82) | 31 | 38 | 72 | |
| rSBA-MenW-135, PRE[M60], $\geq 1:8$ (N=31;37;78) | 7 | 10 | 3 | |
| rSBA-MenW-135, PRE[M60], $\geq 1:128$ (N=31;37;78) | 4 | 7 | 3 | |
| rSBA-MenW-135, POST[M61], $\geq 1:8$ (N=31;38;82) | 31 | 38 | 82 | |
| rSBA-MenW-135, POST[M61], $\geq 1:128$ (N=31;38;82) | 31 | 38 | 81 | |
| rSBA-MenY, PRE[M60], $\geq 1:8$ (N=30;37;78) | 16 | 18 | 23 | |
| rSBA-MenY, PRE[M60], $\geq 1:128$ (N=30;37;78) | 10 | 12 | 23 | |
| rSBA-MenY, POST[M61], $\geq 1:8$ (N=31;38;82) | 31 | 38 | 82 | |
| rSBA-MenY, POST[M61], $\geq 1:128$ (N=31;38;82) | 31 | 38 | 82 | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titers

| | |
|-----------------|----------------------|
| End point title | rSBA antibody titers |
|-----------------|----------------------|

End point description:

Titers are given as geometric mean titers (GMTs) for the serogroups rSBA-MenA, rSBA-MenC, rSBAMenW-135, and rSBA-MenY respectively, determined by Public Health England [PHE] laboratory assay.

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

End point timeframe:

At Month 60 and 61 (just prior to and one month post-primary vaccination for Nimenrix Naive Group; one month post-booster for Nimenrix 1 and Nimenrix 2 Groups)

| End point values | Nimenrix 1 Booster Group | Nimenrix 2 Booster Group | Nimenrix Naive Group | |
|---|-----------------------------------|-----------------------------------|------------------------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 31 | 38 | 82 | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, PRE[M60], (N=30;37; 78) | 35.9 (16.8 to 76.8) | 35.8 (17.1 to 75) | 8.1 (5.7 to 11.5) | |
| rSBA-MenA, POST[M61], (N=31;38; 81) | 5238.1 (3835.3 to 7154.1) | 5287.7 (4212.4 to 6637.4) | 2970.7 (2282.6 to 3866.1) | |
| rSBA-MenC, PRE[M60], (N=31;37; 77) | 16 (8.5 to 30) | 20 (10.1 to 39.7) | 5.2 (4.1 to 6.7) | |
| rSBA-MenC, POST[M61], (N=31;38; 82) | 2738.9 (1707.8 to 4392.5) | 3605 (2401.2 to 5412.4) | 525.1 (365.2 to 755.2) | |
| rSBA-MenW-135, PRE[M60], (N=31; 37; 78) | 8.7 (4.9 to 15.5) | 10 (5.7 to 17.7) | 4.7 (3.9 to 5.6) | |
| rSBA-MenW-135, POST[M61], (N=31; 38; 82) | 10713.2 (7632.4 to 15037.4) | 11585.2 (8901.4 to 15078.2) | 5792.6 (4591.7 to 7307.6) | |
| rSBA-MenY, PRE[M60], (N=30;37; 78) | 29.2 (12.8 to 66.3) | 22 (10.8 to 44.9) | 16.6 (9.9 to 27.7) | |
| rSBA-MenY, POST[M61], (N=31;38; 82) | 5601.6 (4181.4 to 7504) | 5098.3 (4044.6 to 6426.5) | 4027.3 (3159 to 5134.4) | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 4-day (Days 0-3) post-vaccination period; Unsolicited adverse events (AEs): during the 31-day (Days 0-30) post-vaccination period; SAEs: during the entire study period (from Day 0 up to Month 54).

Adverse event reporting additional description:

Unsolicited AEs and SAEs were assessed on the Total Vaccinated Cohort. Solicited symptoms were assessed on those subjects from the Total Vaccinated Cohort who returned their symptom sheet.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 17.0 |

Reporting groups

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

Reporting group description:

Vaccine-naive subjects aged 5-6 years were enrolled to receive Nimenrix vaccine as primary vaccination at Year 5.

| | |
|-----------------------|---------------------|
| Reporting group title | Nimenrix 2 Group Y1 |
|-----------------------|---------------------|

Reporting group description:

Subjects who were previously vaccinated with two doses of Nimenrix, one each at 9 and 12 months of age.

| | |
|-----------------------|---------------------|
| Reporting group title | Nimenrix 1 Group Y1 |
|-----------------------|---------------------|

Reporting group description:

Subjects who received 1 dose of Nimenrix vaccine at 12 months of age.

| Serious adverse events | Nimenrix Naive Group | Nimenrix 2 Group Y1 | Nimenrix 1 Group Y1 |
|---|----------------------|---------------------|---------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 46 (0.00%) | 0 / 38 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Humerus fracture | | | |
| subjects affected / exposed | 1 / 100 (1.00%) | 0 / 46 (0.00%) | 0 / 38 (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: 5 %

| Non-serious adverse events | Nimenrix Naive Group | Nimenrix 2 Group Y1 | Nimenrix 1 Group Y1 |
|---|----------------------|---------------------|---------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 67 / 100 (67.00%) | 43 / 46 (93.48%) | 31 / 38 (81.58%) |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 46 / 89 (51.69%) | 21 / 45 (46.67%) | 18 / 36 (50.00%) |
| occurrences (all) | 46 | 21 | 18 |
| Redness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 22 / 89 (24.72%) | 15 / 45 (33.33%) | 10 / 36 (27.78%) |
| occurrences (all) | 22 | 15 | 10 |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 21 / 89 (23.60%) | 9 / 45 (20.00%) | 8 / 36 (22.22%) |
| occurrences (all) | 21 | 9 | 8 |
| Fatigue | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[4] | 18 / 89 (20.22%) | 7 / 45 (15.56%) | 10 / 36 (27.78%) |
| occurrences (all) | 18 | 7 | 10 |
| Gastrointestinal | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[5] | 7 / 89 (7.87%) | 5 / 45 (11.11%) | 4 / 36 (11.11%) |
| occurrences (all) | 7 | 5 | 4 |
| Headache | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[6] | 11 / 89 (12.36%) | 5 / 45 (11.11%) | 4 / 36 (11.11%) |
| occurrences (all) | 11 | 5 | 4 |
| Fever (Axillary) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[7] | 5 / 89 (5.62%) | 2 / 45 (4.44%) | 1 / 36 (2.78%) |
| occurrences (all) | 5 | 2 | 1 |
| Injection site bruising | | | |

| | | | |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 2 / 100 (2.00%) | 1 / 46 (2.17%) | 2 / 38 (5.26%) |
| occurrences (all) | 2 | 1 | 2 |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Only subjects who completed their symptom reporting sheets were taken in consideration for solicited adverse events.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 05 November 2010 | A new cohort of subjects (naïve control group), aged 5-6 years, will be administered a dose of MenACWY-TT vaccine at the same time as the booster vaccination given to ACWY1 and ACWY2 groups to allow for evaluation of the safety and immunogenicity of a primary (naïve control group) and a booster dose (groups ACWY1 and ACWY2) within the same study. |
| 14 December 2011 | The primary objective of this study is to evaluate the antibody persistence at approximately 1 year, 3 years and 5 years post-administration of one or two doses of MenACWY-TT conjugate vaccine when given to healthy toddlers at 9-12 months of age. This study will generate antibody persistence data following administration of MenACWY-TT. In addition, the safety and immunogenicity of a booster dose of MenACWY-TT, administered at 5 years post-primary vaccination will be evaluated. Another cohort of subjects (naïve control group) 5-6 years of age will be administered a dose of MenACWY-TT vaccine at the same time to allow for evaluation of a primary (naïve control group) and booster dose within the same study. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported