

**Clinical trial results:**

A phase III, open, multi-centre, controlled study to evaluate the long-term antibody persistence at 2 years, 3 years and 4 years after a single dose of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroup A, C, W-135, Y- tetanus toxoid conjugate (MenACWY-TT) vaccine versus one dose of Meningitec™ administered in healthy 12 through 23-month old children who were primed in study MenACWY-TT-039 (109670) and to evaluate the immunogenicity and safety of a booster dose of the same meningococcal conjugate vaccine as given in the primary study, 4 years after priming.

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2008-003824-51 |
| Trial protocol | FI |
| Global end of trial date | 10 September 2012 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 |
| This version publication date | 02 May 2016 |
| First version publication date | 13 June 2015 |

Trial information**Trial identification**

| | |
|-----------------------|--------|
| Sponsor protocol code | 112036 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00955682 |
| 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) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000429-PIP01-08 |
| 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 | Interim |
| Date of interim/final analysis | 31 May 2013 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 16 December 2009 |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 September 2012 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Immunogenicity

Persistence

At 24, 36, and 48 months after primary vaccination of toddlers with MenACWY-TT or Meningitec

•To evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rSBA antibody titres $\geq 1:8$ for each of the four serogroups.

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 | 25 August 2009 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy |
| 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 | Finland: 342 |
| Worldwide total number of subjects | 342 |
| EEA total number of subjects | 342 |

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) | 342 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Pre-assignment period milestones

| | |
|------------------------------|-----|
| Number of subjects started | 342 |
| Number of subjects completed | 295 |

Pre-assignment subject non-completion reasons

| | |
|----------------------------|--------------------------------------|
| Reason: Number of subjects | Not fulfilling protocol criteria: 47 |
|----------------------------|--------------------------------------|

Period 1

| | |
|------------------------------|-------------------------|
| Period 1 title | Year 2 Period |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

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

| | |
|------------------|-------------------|
| Arm title | Nimenrix Group Y2 |
|------------------|-------------------|

Arm description: -

| | |
|--|-------------------|
| 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.

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

Dosage and administration details:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| | |
|------------------|---------------------|
| Arm title | Meningitec Group Y2 |
|------------------|---------------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Meningitec™ |
| 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.

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

Dosage and administration details:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| Number of subjects in period 1^[1] | Nimenrix Group Y2 | Meningitec Group Y2 |
|---|-------------------|---------------------|
| Started | 253 | 42 |
| Completed | 253 | 42 |

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

Arms

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

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

Arm description: -

| | |
|--|-------------------|
| 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.

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

Dosage and administration details:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| | |
|------------------|---------------------|
| Arm title | Meningitec Group Y3 |
|------------------|---------------------|

| | |
|--|-------------------|
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | Meningitec™ |
| 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.

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

Dosage and administration details:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| Number of subjects in period 2 | Nimenrix Group Y3 | Meningitec Group Y3 |
|---------------------------------------|-------------------|---------------------|
| Started | 253 | 42 |
| Completed | 273 | 47 |

| | | |
|----------------------------|----|---|
| Joined | 20 | 5 |
| Late return to study visit | 20 | 5 |

Period 3

| | |
|------------------------------|-------------------------|
| Period 3 title | Year 4 Period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|-------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Nimenrix Group Y4 |

Arm description: -

| | |
|--|-------------------|
| 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.

| | |
|--|---------------------|
| Investigational medicinal product name | Priorix-Tetra™ |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| 2 doses administered subcutaneously into the deltoid region of the dominant arm. | |
| Arm title | Meningitec Group Y4 |
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | Meningitec™ |
| 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. | |
| Investigational medicinal product name | Priorix-Tetra™ |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: | |
| 2 doses administered subcutaneously into the deltoid region of the dominant arm. | |

| Number of subjects in period 3^[2] | Nimenrix Group Y4 | Meningitec Group Y4 |
|---|-------------------|---------------------|
| Started | 246 | 48 |
| Completed | 246 | 48 |

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 4

| | |
|------------------------------|---------------------------|
| Period 4 title | Booster Period (Month 49) |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |
| Arms | |
| Are arms mutually exclusive? | Yes |

| | |
|--|-----------------------------------|
| Arm title | Nimenrix Group Booster (Month 49) |
| Arm description: - | |
| 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.

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

Dosage and administration details:

Subjects boosted with one dose of Nimerix 4 years after primary vaccination.

| | |
|--|-------------------------------------|
| Arm title | Meningitec Group Booster (Month 49) |
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | Meningitec™ |
| 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.

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

Dosage and administration details:

Subjects boosted with one dose of Meningitec 4 years after primary vaccination

| Number of subjects in period 4^[3] | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) |
|---|-----------------------------------|-------------------------------------|
| Started | 245 | 48 |
| Completed | 244 | 47 |
| Not completed | 1 | 1 |
| Lost to follow-up | 1 | 1 |

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 5

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

Arms

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

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

Arm description: -

| | |
|----------|--------------|
| 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:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| | |
|--|----------------|
| Investigational medicinal product name | Priorix-Tetra™ |
|--|----------------|

| | |
|--|--|
| 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 | Meningitec Group Y5 |
|------------------|---------------------|

Arm description: -

| | |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

| | |
|--|-------------|
| Investigational medicinal product name | Meningitec™ |
|--|-------------|

| | |
|--|--|
| 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.

| | |
|--|----------------|
| Investigational medicinal product name | Priorix-Tetra™ |
|--|----------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|-----------|
| Pharmaceutical forms | Injection |
|----------------------|-----------|

| | |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

2 doses administered subcutaneously into the deltoid region of the dominant arm.

| Number of subjects in period 5[4] | Nimenrix Group Y5 | Meningitec Group Y5 |
|--|-------------------|---------------------|
| | Started | 239 |
| Completed | 239 | 47 |

Notes:

[4] - 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.

Baseline characteristics

Reporting groups

| | |
|--------------------------------|---------------------|
| Reporting group title | Nimenrix Group Y2 |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Y2 |
| Reporting group description: - | |

| Reporting group values | Nimenrix Group Y2 | Meningitec Group Y2 | Total |
|---|-------------------|---------------------|-------|
| Number of subjects | 253 | 42 | 295 |
| 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 | 40.7 | 41.1 | |
| standard deviation | ± 1.87 | ± 1.74 | - |
| Gender categorical Units: Subjects | | | |
| Female | 120 | 20 | 140 |
| Male | 133 | 22 | 155 |

End points

End points reporting groups

| | |
|--------------------------------|-------------------------------------|
| Reporting group title | Nimenrix Group Y2 |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Y2 |
| Reporting group description: - | |
| Reporting group title | Nimenrix Group Y3 |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Y3 |
| Reporting group description: - | |
| Reporting group title | Nimenrix Group Y4 |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Y4 |
| Reporting group description: - | |
| Reporting group title | Nimenrix Group Booster (Month 49) |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Booster (Month 49) |
| Reporting group description: - | |
| Reporting group title | Nimenrix Group Y5 |
| Reporting group description: - | |
| Reporting group title | Meningitec Group Y5 |
| Reporting group description: - | |

Primary: Number of subjects with serum bactericidal assay/activity against *Neisseria meningitidis* serogroup A, C, W-135 and Y (using baby rabbit complement) titers $\geq 1:8$.

| | |
|-------------------------------------|---|
| End point title | Number of subjects with serum bactericidal assay/activity against <i>Neisseria meningitidis</i> serogroup A, C, W-135 and Y (using baby rabbit complement) titers $\geq 1:8$. ^[1] |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| At Month 24 post Nimenrix™ vaccine. | |

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 Group Y2 | Meningitec Group Y2 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 188 | 30 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M24] (N=181; 28) | 177 | 23 | | |
| rSBA-MenC [M24] (N=186; 29) | 164 | 20 | | |
| rSBA-MenW-135 [M24] (N=188; 29) | 186 | 17 | | |
| rSBA-MenY [M24] (N=188; 30) | 184 | 24 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8.

| | |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8. ^[2] |
|-----------------|---|

End point description:

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

End point timeframe:

At Month 36 post Nimenrix™ vaccine.

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 Group Y3 | Meningitec Group Y3 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 237 | 40 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M36] (N=228; 38) | 224 | 32 | | |
| rSBA-MenC [M36] (N=235; 39) | 210 | 28 | | |
| rSBA-MenW-135 [M36] (N=236; 39) | 232 | 22 | | |
| rSBA-MenY [M36] (N=237; 40) | 231 | 33 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8.

| | |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8. ^[3] |
|-----------------|---|

End point description:

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

End point timeframe:

At Month 48 post Nimenrix™ vaccine.

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 Group Y4 | Meningitec Group Y4 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 195 | 37 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M48] (N=188; 35) | 185 | 29 | | |
| rSBA-MenC [M48] (N=194; 36) | 175 | 24 | | |
| rSBA-MenW-135 [M48] (N=194; 36) | 192 | 22 | | |
| rSBA-MenY [M48] (N=195; 37) | 190 | 31 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$.

| | |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$. ^[4] |
|-----------------|--|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At Month 36 post primary dose and pre-booster vaccination.

Notes:

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

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

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 262 | 46 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M36] (N=262; 46) | 157 | 3 | | |
| rSBA-MenC [M36] (N=262; 46) | 94 | 6 | | |
| rSBA-MenW-135 [M36] (N=261; 46) | 130 | 2 | | |
| rSBA-MenY [M36] (N=262; 46) | 141 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8.

| | |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8. ^[5] |
|-----------------|---|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At Month 48 post primary dose and pre-booster vaccination.

Notes:

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

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

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 225 | 45 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M48] (N=224; 45) | 166 | 13 | | |
| rSBA-MenC [M48] (N=225; 45) | 91 | 16 | | |
| rSBA-MenW-135 [M48] (N=225; 45) | 111 | 7 | | |
| rSBA-MenY [M48] (N=225; 45) | 131 | 11 | | |

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 1:128.

| | |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 24 post primary dose.

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 188 | 30 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M24] (N=181; 28) | 166 | 16 | | |
| rSBA-MenC [M24] (N=186; 29) | 90 | 14 | | |
| rSBA-MenW-135 [M24] (N=188; 29) | 171 | 12 | | |
| rSBA-MenY [M24] (N=188; 30) | 154 | 20 | | |

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 1:128.

| | |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 36 post primary dose.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 237 | 40 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M36] (N=228; 38) | 207 | 23 | | |
| rSBA-MenC [M36] (N=235; 39) | 115 | 19 | | |
| rSBA-MenW-135 [M36] (N=236; 39) | 211 | 16 | | |
| rSBA-MenY [M36] (N=237; 40) | 195 | 26 | | |

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 1:128.

| | |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128. |
|-----------------|--|

End point description:

| | |
|--------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 48 post primary dose. | |

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 195 | 37 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M48] (N=188; 35) | 175 | 22 | | |
| rSBA-MenC [M48] (N=194; 36) | 97 | 18 | | |
| rSBA-MenW-135 [M48] (N=194; 36) | 177 | 17 | | |
| rSBA-MenY [M48] (N=195; 37) | 163 | 25 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

| | |
|---------------------------------|---|
| End point title | rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers. |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| At Months 24 post primary dose. | |

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|--|------------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 188 | 30 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M24] (N=181; 28) | 420.3 (356.1 to 495.9) | 90.6 (46.2 to 177.9) | | |
| rSBA-MenC [M24] (N=186; 29) | 98.1 (77.7 to 123.8) | 53.5 (25.5 to 112) | | |
| rSBA-MenW-135 [M24] (N=188; 29) | 396.9 (342 to 460.5) | 42.2 (18.5 to 96.4) | | |
| rSBA-MenY [M24] (N=188; 30) | 396.6 (324 to 485.5) | 151.3 (69.2 to 330.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

End point title rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

End point description:

End point type Secondary

End point timeframe:

At Month 36 post primary dose.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|--|------------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 237 | 40 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M36] (N=228; 38) | 415.3 (360.9 to 478) | 102.3 (59.6 to 175.4) | | |
| rSBA-MenC [M36] (N=235; 39) | 104.2 (84.7 to 128.2) | 58.5 (31.7 to 107.9) | | |
| rSBA-MenW-135 [M36] (N=236; 39) | 372.4 (323.4 to 428.9) | 39.7 (19.5 to 80.5) | | |
| rSBA-MenY [M36] (N=237; 40) | 405.4 (337.4 to 487.1) | 169.1 (89.6 to 319.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

End point title rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

End point description:

End point type Secondary

End point timeframe:

At Month 48 post primary dose.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|------------------------|-----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 195 | 27 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M48] (N=188; 35) | 437.1 (376.6 to 507.4) | 106.4 (58.8 to 192.4) | | |
| rSBA-MenC [M48] (N=194; 36) | 105.4 (84.6 to 131.3) | 53.6 (27.1 to 105.8) | | |
| rSBA-MenW-135 [M48] (N=194; 36) | 398.2 (343.1 to 462.1) | 49.1 (23.5 to 102.5) | | |
| rSBA-MenY [M48] (N=195; 37) | 411.1 (336.1 to 502.9) | 186.9 (98.1 to 355.8) | | |

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 1:128.

| | |
|------------------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128. |
| End point description: | rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). |
| End point type | Secondary |
| End point timeframe: | At Month 36 post primary dose and pre-booster vaccination. |

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 262 | 46 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M36] (N=262; 46) | 60 | 3 | | |
| rSBA-MenC [M36] (N=262; 46) | 23 | 3 | | |
| rSBA-MenW-135 [M36] (N=261; 46) | 87 | 2 | | |
| rSBA-MenY [M36] (N=262; 46) | 75 | 2 | | |

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 1:128.

| | |
|--|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:128$. |
| End point description: rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). | |
| End point type | Secondary |
| End point timeframe: At Month 48 post primary dose and pre-booster vaccination. | |

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|---------------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 225 | 45 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M48] (N=224; 45) | 134 | 12 | | |
| rSBA-MenC [M48] (N=225; 45) | 34 | 10 | | |
| rSBA-MenW-135 [M48] (N=225; 45) | 88 | 7 | | |
| rSBA-MenY [M48] (N=225; 45) | 91 | 9 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

| | |
|--|---|
| End point title | rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers. |
| End point description: rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). | |
| End point type | Secondary |
| End point timeframe: At Months 36 post primary dose and pre-booster vaccination. | |

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 262 | 46 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M36] (N=262; 46) | 19.3 (15.7 to 23.6) | 5.2 (3.8 to 6.9) | | |
| rSBA-MenC [M36] (N=262; 46) | 9.8 (8.1 to 11.7) | 5.7 (4.2 to 7.7) | | |
| rSBA-MenW-135 [M36] (N=261; 46) | 24.9 (19.2 to 32.4) | 4.9 (3.7 to 6.7) | | |

| | | | | |
|-----------------------------|---------------------|------------------|--|--|
| rSBA-MenY [M36] (N=262; 46) | 22.3 (17.6 to 28.4) | 5.7 (4.2 to 7.8) | | |
|-----------------------------|---------------------|------------------|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

| | |
|------------------------|--|
| End point title | rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers. |
| End point description: | rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). |
| End point type | Secondary |
| End point timeframe: | At Month 48 post primary dose and pre-booster vaccination. |

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|-----------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 225 | 45 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M48] (N=224; 45) | 107.3 (77.6 to 148.3) | 18.4 (8.5 to 39.7) | | |
| rSBA-MenC [M48] (N=225; 45) | 12.3 (9.8 to 15.3) | 13.5 (7.4 to 24.5) | | |
| rSBA-MenW-135 [M48] (N=225; 45) | 30.5 (22.4 to 41.5) | 8 (4.8 to 13.3) | | |
| rSBA-MenY [M48] (N=225; 45) | 36.2 (27.1 to 48.4) | 10.4 (6 to 18) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay/activity against Neisseria meningitidis serogroup A, C, W-135 and Y (using human complement) titers \geq 1:4 and 1:8.

| | |
|------------------------|--|
| End point title | Number of subjects with serum bactericidal assay/activity against Neisseria meningitidis serogroup A, C, W-135 and Y (using human complement) titers \geq 1:4 and 1:8. |
| End point description: | |
| End point type | Secondary |

End point timeframe:
At Month 24 post primary dose.

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 183 | 23 | | |
| Units: Subjects | | | | |
| hSBA-MenA [M24], $\geq 1:4$ (N=183; 23) | 46 | 2 | | |
| hSBA-MenA [M24], $\geq 1:8$ (N=183; 23) | 42 | 0 | | |
| hSBA-MenC [M24], $\geq 1:4$ (N=175; 19) | 154 | 11 | | |
| hSBA-MenC [M24], $\geq 1:8$ (N=175; 19) | 152 | 10 | | |
| hSBA-MenW-135 [M24], $\geq 1:4$ (N=180; 23) | 167 | 0 | | |
| hSBA-MenW-135 [M24], $\geq 1:8$ (N=180; 23) | 164 | 0 | | |
| hSBA-MenY [M24], $\geq 1:4$ (N=154; 22) | 134 | 5 | | |
| hSBA-MenY [M24], $\geq 1:8$ (N=154; 22) | 134 | 5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay/activity against *Neisseria meningitidis* serogroup A, C, W-135 and Y (using human complement) titers $\geq 1:4$ and $1:8$.

| | |
|-----------------|--|
| End point title | Number of subjects with serum bactericidal assay/activity against <i>Neisseria meningitidis</i> serogroup A, C, W-135 and Y (using human complement) titers $\geq 1:4$ and $1:8$. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 36 post primary dose.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 258 | 35 | | |
| Units: Subjects | | | | |
| hSBA-MenA [M36], $\geq 1:4$ (N=251; 31) | 95 | 5 | | |
| hSBA-MenA [M36], $\geq 1:8$ (N=251; 31) | 90 | 4 | | |
| hSBA-MenC [M36], $\geq 1:4$ (N=253; 31) | 204 | 13 | | |
| hSBA-MenC [M36], $\geq 1:8$ (N=253; 31) | 198 | 13 | | |
| hSBA-MenW-135 [M36], $\geq 1:4$ (N=254; 33) | 209 | 2 | | |

| | | | | |
|---|-----|---|--|--|
| hSBA-MenW-135 [M36], $\geq 1:8$ (N=254; 33) | 209 | 2 | | |
| hSBA-MenY [M36], $\geq 1:4$ (N=250; 33) | 184 | 6 | | |
| hSBA-MenY [M36], $\geq 1:8$ (N=250; 33) | 180 | 6 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay/activity against *Neisseria meningitidis* serogroup A, C, W-135 and Y (using human complement) titers $\geq 1:4$ and $1:8$.

| | |
|-----------------|--|
| End point title | Number of subjects with serum bactericidal assay/activity against <i>Neisseria meningitidis</i> serogroup A, C, W-135 and Y (using human complement) titers $\geq 1:4$ and $1:8$. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 48 post primary dose.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 209 | 32 | | |
| Units: Subjects | | | | |
| hSBA-MenA [M48], $\geq 1:4$ (N=198; 28) | 58 | 4 | | |
| hSBA-MenA [M48], $\geq 1:8$ (N=198; 28) | 57 | 4 | | |
| hSBA-MenC [M48], $\geq 1:4$ (N=209; 32) | 154 | 15 | | |
| hSBA-MenC [M48], $\geq 1:8$ (N=209; 32) | 153 | 15 | | |
| hSBA-MenW-135 [M48], $\geq 1:4$ (N=165; 26) | 134 | 2 | | |
| hSBA-MenW-135 [M48], $\geq 1:8$ (N=165; 26) | 133 | 2 | | |
| hSBA-MenY [M48], $\geq 1:4$ (N=130; 27) | 85 | 6 | | |
| hSBA-MenY [M48], $\geq 1:8$ (N=130; 27) | 85 | 6 | | |

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:

| | |
|--------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| At Month 24 post primary dose. | |

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 182 | 23 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA [M24] (N=183; 23) | 3.8 (3.2 to 4.5) | 2.2 (1.9 to 2.4) | | |
| hSBA-MenC [M24] (N=175; 19) | 50.2 (38.7 to 65.1) | 10.4 (4.7 to 22.8) | | |
| hSBA-MenW-135 [M24] (N=180; 23) | 77.7 (61.8 to 97.6) | 2 (2 to 2) | | |
| hSBA-MenY [M24] (N=154; 22) | 58.1 (44.5 to 75.8) | 5 (2.2 to 11.1) | | |

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: | |
| End point type | Secondary |
| End point timeframe: | |
| At Month 36 post primary dose. | |

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 254 | 33 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA [M36] (N=251; 31) | 5.8 (4.8 to 7) | 2.6 (2.1 to 3.3) | | |
| hSBA-MenC [M36] (N=253; 31) | 37.8 (29.4 to 48.6) | 6.2 (3.7 to 10.3) | | |
| hSBA-MenW-135 [M36] (N=254; 33) | 52 (41.4 to 65.2) | 2.4 (1.8 to 3.1) | | |
| hSBA-MenY [M36] (N=250; 33) | 33.2 (25.9 to 42.5) | 4.1 (2.4 to 7.1) | | |

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:

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

End point timeframe:

At Month 48 post primary dose.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 209 | 32 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA [M48] (N=198; 28) | 4.9 (4 to 6) | 2.9 (2 to 4) | | |
| hSBA-MenC [M48] (N=209; 32) | 32 (23.8 to 43) | 11.3 (4.9 to 25.6) | | |
| hSBA-MenW-135 [M48] (N=165; 26) | 47.1 (35.7 to 62.2) | 2.6 (1.8 to 3.8) | | |
| hSBA-MenY [M48] (N=130; 27) | 29.8 (20.2 to 44.1) | 4.4 (2.4 to 8.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 24 post primary dose.

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|--|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 92 | 17 | | |
| Units: Subjects | | | | |
| Anti-PSA [24], ≥ 0.3 (N=92; 17) | 50 | 5 | | |
| Anti-PSA [24], ≥ 2.0 (N=92; 17) | 8 | 2 | | |
| Anti-PSC [24], ≥ 0.3 (N=89; 16) | 25 | 3 | | |
| Anti-PSC [24], ≥ 2.0 (N=89; 16) | 0 | 0 | | |
| Anti-PSW-135 [24], ≥ 0.3 (N=86; 16) | 56 | 0 | | |
| Anti-PSW-135 [24], ≥ 2.0 (N=86; 16) | 8 | 0 | | |
| Anti-PSY [24], ≥ 0.3 (N=89; 17) | 72 | 0 | | |
| Anti-PSY [24], ≥ 2.0 (N=89; 17) | 25 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|------------------------|--|
| End point title | Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | At Month 36 post primary dose. |

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 114 | 21 | | |
| Units: Subjects | | | | |
| Anti-PSA [36], ≥ 0.3 (N=114; 21) | 61 | 6 | | |
| Anti-PSA [36], ≥ 2.0 (N=114; 21) | 10 | 2 | | |
| Anti-PSC [36], ≥ 0.3 (N=111; 20) | 28 | 4 | | |
| Anti-PSC [36], ≥ 2.0 (N=111; 20) | 0 | 0 | | |
| Anti-PSW-135 [36], ≥ 0.3 (N=106; 20) | 68 | 0 | | |
| Anti-PSW-135 [36], ≥ 2.0 (N=106; 20) | 11 | 0 | | |
| Anti-PSY [36], ≥ 0.3 (N=110; 21) | 89 | 1 | | |
| Anti-PSY [36], ≥ 2.0 (N=110; 21) | 33 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 48 post primary dose.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 20 | | |
| Units: Subjects | | | | |
| Anti-PSA [48], ≥ 0.3 (N=93; 20) | 50 | 5 | | |
| Anti-PSA [48], ≥ 2.0 (N=93; 20) | 9 | 2 | | |
| Anti-PSC [48], ≥ 0.3 (N=91; 19) | 21 | 3 | | |
| Anti-PSC [48], ≥ 2.0 (N=91; 19) | 0 | 0 | | |
| Anti-PSW-135 [48], ≥ 0.3 (N=86; 19) | 55 | 0 | | |
| Anti-PSW-135 [48], ≥ 2.0 (N=86; 19) | 8 | 0 | | |
| Anti-PSY [48], ≥ 0.3 (N=90; 20) | 73 | 1 | | |
| Anti-PSY [48], ≥ 2.0 (N=90; 20) | 26 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|-----------------|---|
| End point title | Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
|-----------------|---|

End point description:

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

End point timeframe:

At Month 24 post primary dose.

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 92 | 17 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [24] (N=92; 17) | 0.4 (0.32 to 0.5) | 0.28 (0.16 to 0.49) | | |
| Anti-PSC [24] (N=89; 16) | 0.22 (0.19 to 0.25) | 0.19 (0.14 to 0.27) | | |
| Anti-PSW-135 [24] (N=86; 16) | 0.47 (0.37 to 0.59) | 0.15 (0.15 to 0.15) | | |
| Anti-PSY [24] (N=89; 17) | 0.85 (0.65 to 1.12) | 0.15 (0.15 to 0.15) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|--------------------------------|---|
| End point title | Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| At Month 36 post primary dose. | |

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 114 | 21 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [36] (N=114; 21) | 0.39 (0.32 to 0.48) | 0.27 (0.17 to 0.43) | | |
| Anti-PSC [36] (N=111; 20) | 0.21 (0.19 to 0.24) | 0.19 (0.15 to 0.25) | | |
| Anti-PSW-135 [36] (N=106; 20) | 0.48 (0.39 to 0.59) | 0.15 (0.15 to 0.15) | | |
| Anti-PSY [36] (N=110; 21) | 0.89 (0.7 to 1.14) | 0.16 (0.14 to 0.17) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|-----------------|---|
| End point title | Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
|-----------------|---|

End point description:

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

End point timeframe:

At Month 48 post primary dose.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 93 | 20 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [48] (N=93; 20) | 0.39 (0.31 to 0.5) | 0.26 (0.16 to 0.42) | | |
| Anti-PSC [48] (N=91; 19) | 0.2 (0.18 to 0.23) | 0.19 (0.14 to 0.25) | | |
| Anti-PSW-135 [48] (N=86; 19) | 0.46 (0.37 to 0.58) | 0.15 (0.15 to 0.15) | | |
| Anti-PSY [48] (N=90; 20) | 0.89 (0.68 to 1.15) | 0.16 (0.14 to 0.17) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At month 36 post primary dose an pre-booster vaccination.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 130 | 26 | | |
| Units: Subjects | | | | |
| Anti-PSA [36], ≥ 0.3 (N=130; 26) | 128 | 20 | | |
| Anti-PSA [36], ≥ 2.0 (N=130; 26) | 27 | 3 | | |
| Anti-PSC [36], ≥ 0.3 (N=119; 25) | 37 | 5 | | |
| Anti-PSC [36], ≥ 2.0 (N=119; 25) | 2 | 1 | | |
| Anti-PSW-135 [36], ≥ 0.3 (N=122; 25) | 117 | 11 | | |
| Anti-PSW-135 [36], ≥ 2.0 (N=122; 25) | 13 | 0 | | |
| Anti-PSY [36], ≥ 0.3 (N=104; 22) | 102 | 19 | | |
| Anti-PSY [36], ≥ 2.0 (N=104; 22) | 19 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At Month 48 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 56 | 22 | | |
| Units: Subjects | | | | |
| Anti-PSA [48], ≥ 0.3 (N=53; 22) | 53 | 20 | | |
| Anti-PSA [48], ≥ 2.0 (N=53; 22) | 26 | 9 | | |
| Anti-PSC [48], ≥ 0.3 (N=56; 21) | 16 | 7 | | |
| Anti-PSC [48], ≥ 2.0 (N=56; 21) | 3 | 3 | | |
| Anti-PSW-135 [48], ≥ 0.3 (N=56; 22) | 56 | 17 | | |
| Anti-PSW-135 [48], ≥ 2.0 (N=56; 22) | 5 | 0 | | |
| Anti-PSY [48], ≥ 0.3 (N=50; 20) | 48 | 18 | | |
| Anti-PSY [48], ≥ 2.0 (N=50; 20) | 7 | 3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|-----------------|---|
| End point title | Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
|-----------------|---|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At Month 36 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 130 | 26 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [36] (N=130; 26) | 1.16 (1.01 to 1.34) | 0.69 (0.45 to 1.06) | | |
| Anti-PSC [36] (N=119; 25) | 0.22 (0.2 to 0.25) | 0.19 (0.15 to 0.25) | | |
| Anti-PSW-135 [36] (N=122; 25) | 0.78 (0.69 to 0.89) | 0.24 (0.19 to 0.3) | | |
| Anti-PSY [36] (N=104; 22) | 1.12 (0.97 to 1.29) | 0.52 (0.37 to 0.72) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|-----------------|---|
| End point title | Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
|-----------------|---|

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At Month 48 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 106 | 24 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [48] (N=53; 22) | 2.05 (1.61 to 2.61) | 1.65 (0.97 to 2.83) | | |
| Anti-PSC [48] (N=56; 21) | 0.25 (0.19 to 0.33) | 0.31 (0.18 to 0.54) | | |
| Anti-PSW-135 [48] (N=56; 22) | 0.85 (0.73 to 0.98) | 0.35 (0.28 to 0.46) | | |
| Anti-PSY [48] (N=50; 20) | 0.77 (0.63 to 0.93) | 0.83 (0.54 to 1.28) | | |

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 above the cut-off values.

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

End point description:

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

End point timeframe:

At Month 12 post booster dose (Month 60).

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 227 | 46 | | |
| Units: Subjects | | | | |
| rSBA-MenA, PRE [M60], ≥ 1:8 (N=106; 22) | 35 | 6 | | |
| rSBA-MenA, PRE [M60], ≥ 1:28 (N=106; 22) | 24 | 2 | | |
| rSBA-MenA, POST [M60], ≥ 1:8 (N=227; 22) | 227 | 12 | | |
| rSBA-MenA, POST [M60], ≥ 1:28 (N=227; 22) | 227 | 7 | | |
| rSBA-MenC, PRE [M60], ≥ 1:8 (N=107; 19) | 31 | 6 | | |

| | | | | |
|---|-----|----|--|--|
| rSBA-MenC, PRE [M60], $\geq 1:28$ (N=107; 19) | 14 | 1 | | |
| rSBA-MenC, POST [M60], $\geq 1:8$ (N=226; 46) | 226 | 44 | | |
| rSBA-MenC, POST [M60], $\geq 1:28$ (N=226; 46) | 214 | 25 | | |
| rSBA-MenW-135, PRE [M60], $\geq 1:8$ (N=117; 27) | 57 | 14 | | |
| rSBA-MenW-135, PRE [M60], $\geq 1:28$ (N=117; 27) | 25 | 7 | | |
| rSBA-MenW-135, POST [M60], $\geq 1:8$ (N=227; 24) | 227 | 15 | | |
| rSBA-MenW-135, POST [M60], $\geq 1:28$ (N=227; 24) | 227 | 6 | | |
| rSBA-MenY, PRE [M60], $\geq 1:8$ (N=122; 27) | 76 | 19 | | |
| rSBA-MenY, PRE [M60], $\geq 1:28$ (N=122; 27) | 52 | 14 | | |
| rSBA-MenY, POST [M60], $\geq 1:8$ (N=226; 26) | 226 | 26 | | |
| rSBA-MenY, POST [M60], $\geq 1:28$ (N=226; 26) | 226 | 13 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

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

End point description:

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

End point timeframe:

At Month 12 post booster dose (Month 60).

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|---------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 227 | 46 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA, PRE [M60] (N=106; 22) | 14.1 (9.8 to 20.4) | 9.5 (4.8 to 18.8) | | |
| rSBA-MenA, POST [M60] (N=227; 22) | 2040.1 (1829.1 to 2275.3) | 27 (11.8 to 61.4) | | |
| rSBA-MenC, PRE [M60] (N=107; 19) | 10.6 (7.8 to 14.5) | 9.3 (4.9 to 17.9) | | |
| rSBA-MenC, POST [M60] (N=226; 46) | 472 (422.2 to 527.7) | 151.9 (102.2 to 225.8) | | |

| | | | | |
|---------------------------------------|---------------------------|----------------------|--|--|
| rSBA-MenW-135, PRE [M60] (N=117; 27) | 19.3 (14.1 to 26.5) | 26.3 (11.8 to 58.5) | | |
| rSBA-MenW-135, POST [M60] (N=227; 24) | 2351 (2104.8 to 2625.8) | 33.9 (15.1 to 76.2) | | |
| rSBA-MenY, PRE [M60] (N=122; 27) | 50.3 (34.5 to 73.5) | 71.4 (31.2 to 163.2) | | |
| rSBA-MenY, POST [M60] (N=226; 26) | 2633.8 (2327.4 to 2980.7) | 77.2 (33.6 to 177.3) | | |

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 above the cut-off values.

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

End point description:

rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At one month (Month 49) post booster dose.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|--|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 215 | 43 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M49], $\geq 1:8$ (N=214; 43) | 214 | 9 | | |
| rSBA-MenA [M49], $\geq 1:28$ (N=214; 43) | 214 | 8 | | |
| rSBA-MenC [M49], $\geq 1:8$ (N=215; 43) | 215 | 43 | | |
| rSBA-MenC [M49], $\geq 1:28$ (N=215; 43) | 215 | 43 | | |
| rSBA-MenW-135 [M49], $\geq 1:8$ (N=215; 43) | 215 | 8 | | |
| rSBA-MenW-135 [M49], $\geq 1:28$ (N=215; 43) | 215 | 7 | | |
| rSBA-MenY [M49], $\geq 1:8$ (N=215; 43) | 215 | 14 | | |
| rSBA-MenY [M49], $\geq 1:28$ (N=215; 43) | 215 | 14 | | |

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 above the cut-off values.

| | |
|--|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers above the cut-off values. |
| End point description: rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). | |
| End point type | Secondary |
| End point timeframe: At 12 months (Month 60) post booster dose. | |

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 236 | 46 | | |
| Units: Subjects | | | | |
| rSBA-MenA [M60], $\geq 1:8$ (N=231; 46) | 231 | 3 | | |
| rSBA-MenA [M60], $\geq 1:28$ (N=231; 46) | 229 | 3 | | |
| rSBA-MenC [M60], $\geq 1:8$ (N=226; 46) | 225 | 45 | | |
| rSBA-MenC [M60], $\geq 1:28$ (N=226; 46) | 181 | 40 | | |
| rSBA-MenW-135 [M60], $\geq 1:8$ (N=231; 46) | 231 | 2 | | |
| rSBA-MenW-135 [M60], $\geq 1:28$ (N=231; 46) | 229 | 2 | | |
| rSBA-MenY [M60], $\geq 1:8$ (N=231; 46) | 231 | 11 | | |
| rSBA-MenY [M60], $\geq 1:28$ (N=231; 46) | 229 | 11 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

| | |
|--|---|
| End point title | rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers. |
| End point description: rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). | |
| End point type | Secondary |
| End point timeframe: At one month (Month 49) post booster dose. | |

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|--|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 215 | 43 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|---------------------------------|-----------------------------|-----------------------|--|--|
| rSBA-MenA [M49] (N=214; 43) | 7173.3 (6389.2 to 8053.5) | 10.7 (5.6 to 20.4) | | |
| rSBA-MenC [M49] (N=215; 43) | 4511.9 (3935.9 to 5172.3) | 3718.4 (2596 to 5326) | | |
| rSBA-MenW-135 [M49] (N=215; 43) | 10949.7 (9531.4 to 12579.1) | 9.6 (5.3 to 17.3) | | |
| rSBA-MenY [M49] (N=215; 43) | 4585.3 (4128.6 to 5092.5) | 15 (8 to 28) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers.

| | |
|------------------------|--|
| End point title | rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers. |
| End point description: | rSBA-MenA results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). |
| End point type | Secondary |
| End point timeframe: | At 12 months (Month 60) post booster dose. |

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|---------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 231 | 46 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| rSBA-MenA [M60] (N=231; 46) | 978.9 (860.2 to 1114) | 5.4 (3.8 to 7.6) | | |
| rSBA-MenC [M60] (N=226; 46) | 226.4 (183.7 to 279) | 320.9 (201.1 to 512.2) | | |
| rSBA-MenW-135 [M60] (N=231; 46) | 1390.7 (1203.2 to 1607.3) | 4.7 (3.8 to 5.7) | | |
| rSBA-MenY [M60] (N=231; 46) | 1071.1 (924.9 to 1240.5) | 13.4 (6.9 to 25.8) | | |

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 above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers above the cut-off values. |
|-----------------|--|

End point description:

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

End point timeframe:

At one month (Month 49) post booster dose.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|---|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 209 | 33 | | |
| Units: Subjects | | | | |
| hSBA-MenA [M49], $\geq 1:4$ (N=202; 28) | 201 | 4 | | |
| hSBA-MenA [M49], $\geq 1:8$ (N=202; 28) | 201 | 4 | | |
| hSBA-MenC [M49], $\geq 1:4$ (N=209; 33) | 209 | 33 | | |
| hSBA-MenC [M49], $\geq 1:8$ (N=209; 33) | 209 | 33 | | |
| hSBA-MenW-135 [M49], $\geq 1:4$ (N=192; 25) | 192 | 1 | | |
| hSBA-MenW-135 [M49], $\geq 1:8$ (N=192; 25) | 192 | 1 | | |
| hSBA-MenY [M49], $\geq 1:4$ (N=173; 25) | 173 | 6 | | |
| hSBA-MenY [M49], $\geq 1:8$ (N=173; 25) | 173 | 6 | | |

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 above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titers above the cut-off values. |
|-----------------|--|

End point description:

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

End point timeframe:

At 12 months (Month 60) post booster dose.

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|---|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 228 | 33 | | |
| Units: Subjects | | | | |
| hSBA-MenA [M60], $\geq 1:4$ (N=221; 28) | 211 | 3 | | |
| hSBA-MenA [M60], $\geq 1:8$ (N=221; 28) | 211 | 3 | | |
| hSBA-MenC [M60], $\geq 1:4$ (N=228; 33) | 228 | 33 | | |
| hSBA-MenC [M60], $\geq 1:8$ (N=228; 33) | 228 | 33 | | |
| hSBA-MenW-135 [M60], $\geq 1:4$ (N=218; 31) | 218 | 5 | | |
| hSBA-MenW-135 [M60], $\geq 1:8$ (N=218; 31) | 218 | 5 | | |
| hSBA-MenY [M60], $\geq 1:4$ (N=206; 31) | 206 | 10 | | |
| hSBA-MenY [M60], $\geq 1:8$ (N=206; 31) | 206 | 10 | | |

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: | |
| End point type | Secondary |
| End point timeframe: | At one month (Month 49) post booster dose. |

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|--|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 209 | 33 | | |
| Units: Titres | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA [M49] (N=202; 28) | 1343.2 (1119.3 to 1612) | 2.8 (2 to 3.8) | | |
| hSBA-MenC [M49] (N=209; 33) | 15831.4 (13625.8 to 18394) | 8646.1 (5886.6 to 12699.3) | | |
| hSBA-MenW-135 [M49] (N=192; 25) | 14411.2 (12971.8 to 16010.2) | 2.3 (1.7 to 3.3) | | |
| hSBA-MenY [M49] (N=173; 25) | 6775.5 (5961.3 to 7700.9) | 4.9 (2.4 to 9.8) | | |

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:

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

End point timeframe:

At 12 months (Month 60) post booster dose.

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|---------------------------|-------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 228 | 33 | | |
| Units: Tires | | | | |
| geometric mean (confidence interval 95%) | | | | |
| hSBA-MenA [M60] (N=221; 28) | 88 (73.6 to 105.1) | 2.5 (1.9 to 3.2) | | |
| hSBA-MenC [M60] (N=228; 33) | 1342.3 (1134.6 to 1588.1) | 931.1 (572.8 to 1513.4) | | |
| hSBA-MenW-135 [M60] (N=218; 31) | 2196.6 (1955.7 to 2467.2) | 3.4 (2.2 to 5.4) | | |
| hSBA-MenY [M60] (N=206; 31) | 1110.8 (987.5 to 1249.6) | 7.5 (3.6 to 15.7) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

Anti-PS results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At one month (Month 49) post booster dose.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|--|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 70 | 19 | | |
| Units: Subjects | | | | |
| Anti-PSA [49], ≥ 0.3 (N=67; 15) | 67 | 15 | | |
| Anti-PSA [49], ≥ 2.0 (N=67; 15) | 66 | 6 | | |
| Anti-PSC [49], ≥ 0.3 (N=70; 18) | 70 | 18 | | |
| Anti-PSC [49], ≥ 2.0 (N=70; 18) | 67 | 18 | | |
| Anti-PSW-135 [49], ≥ 0.3 (N=69; 19) | 69 | 13 | | |
| Anti-PSW-135 [49], ≥ 2.0 (N=69; 19) | 69 | 0 | | |
| Anti-PSY [49], ≥ 0.3 (N=64; 10) | 63 | 9 | | |
| Anti-PSY [49], ≥ 2.0 (N=64; 10) | 63 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY above the cut-off values.

| | |
|-----------------|--|
| End point title | Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY above the cut-off values. |
|-----------------|--|

End point description:

Anti-PS results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE).

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

End point timeframe:

At 12 months (Month 60) post booster dose.

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|------------------------------|--------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 22 | | |
| Units: Subjects | | | | |
| Anti-PSA [60], ≥ 0.3 (N=98; 22) | 98 | 22 | | |
| Anti-PSA [60], ≥ 2.0 (N=98; 22) | 82 | 5 | | |
| Anti-PSC [60], ≥ 0.3 (N=85; 14) | 85 | 13 | | |
| Anti-PSC [60], ≥ 2.0 (N=85; 14) | 38 | 10 | | |
| Anti-PSW-135 [60], ≥ 0.3 (N=98; 22) | 98 | 8 | | |
| Anti-PSW-135 [60], ≥ 2.0 (N=98; 22) | 98 | 0 | | |
| Anti-PSY [60], ≥ 0.3 (N=86; 12) | 85 | 12 | | |

| | | | | |
|--------------------------------------|----|---|--|--|
| Anti-PSY [60], ≥ 2.0 (N=86; 12) | 85 | 6 | | |
|--------------------------------------|----|---|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|------------------------|--|
| End point title | Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
| End point description: | Anti-PS results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). |
| End point type | Secondary |
| End point timeframe: | At one month (Month 49) post booster dose. |

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|--|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 70 | 19 | | |
| Units: $\mu\text{g/mL}$ | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [49] (N=67; 15) | 12.61 (10.39 to 15.29) | 1.76 (1.1 to 2.81) | | |
| Anti-PSC [49] (N=70; 18) | 8.64 (7.18 to 10.4) | 13.07 (9.09 to 18.8) | | |
| Anti-PSW-135 [49] (N=69; 19) | 59.06 (49.26 to 70.81) | 0.34 (0.24 to 0.48) | | |
| Anti-PSY [49] (N=64; 10) | 38.85 (30.2 to 49.98) | 0.56 (0.35 to 0.89) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations.

| | |
|------------------------|--|
| End point title | Anti-PSA, anti-PSC, anti-PSW, and anti-PSY antibody concentrations. |
| End point description: | Anti-PS results for the Year 3 and Year 4 time points obtained by re-testing the samples in parallel at Public Health England (PHE). |
| End point type | Secondary |

End point timeframe:

At 12 months (Month 60) post booster dose.

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|--|-----------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 98 | 22 | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-PSA [60] (N=98; 22) | 4.22 (3.64 to 4.88) | 1.41 (1.09 to 1.82) | | |
| Anti-PSC [60] (N=85; 14) | 1.81 (1.56 to 2.11) | 2.93 (1.47 to 5.86) | | |
| Anti-PSW-135 [60] (N=98; 22) | 9.44 (8.29 to 10.74) | 0.26 (0.18 to 0.37) | | |
| Anti-PSY [60] (N=86; 12) | 10.31 (8.64 to 12.29) | 2.24 (1.25 to 4.02) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited local symptoms.

End point title | Number of subjects reporting any solicited local symptoms.

End point description:

End point type | Secondary

End point timeframe:

During the 8-day period (Days 0-7) after booster vaccination.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|-----------------------------|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 244 | 47 | | |
| Units: Subjects | | | | |
| Any pain | 149 | 23 | | |
| Any Redness | 90 | 17 | | |
| Any Swelling | 70 | 11 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting any solicited general symptoms.

End point title | Number of subjects reporting any solicited general symptoms.

End point description:

End point type | Secondary

End point timeframe:

During the 8-day period (Days 0-7) after booster vaccination.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|---|---|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 244 | 47 | | |
| Units: Subjects | | | | |
| Any drowsiness | 41 | 10 | | |
| Any irritability | 40 | 11 | | |
| Any loss of appetite | 31 | 8 | | |
| Any temperature ($\geq 37.5^{\circ}\text{C}$) | 16 | 1 | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

End point type | Secondary

End point timeframe:

During the 31-day period (Days 0-30) after booster vaccination.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|-----------------------------|---|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 245 | 48 | | |
| Units: Subjects | | | | |
| Any AE(s) | 106 | 18 | | |

Statistical analyses

No statistical analyses for this end point

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

End point title | Number of subjects reporting any solicited adverse events (SAEs).

End point description:

End point type | Secondary

End point timeframe:

At Month 24 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y2 | Meningitec Group Y2 | | |
|-----------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 253 | 42 | | |
| Units: Subjects | | | | |
| Any SAE(s) M24 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

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

End point title | Number of subjects reporting any solicited adverse events (SAEs).

End point description:

End point type | Secondary

End point timeframe:

At Month 36 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y3 | Meningitec Group Y3 | | |
|-----------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 273 | 47 | | |
| Units: Subjects | | | | |
| Any SAE(s) M36 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

At Month 48 post primary dose and pre-booster vaccination.

| End point values | Nimenrix Group Y4 | Meningitec Group Y4 | | |
|-----------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 246 | 48 | | |
| Units: Subjects | | | | |
| Any SAE(s) M48 | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

At one month (Month 49) post booster dose.

| End point values | Nimenrix Group Booster (Month 49) | Meningitec Group Booster (Month 49) | | |
|-----------------------------|-----------------------------------|-------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 245 | 48 | | |
| Units: Subjects | | | | |
| Any SAE(s) | 2 | 0 | | |

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

At 12 months (Month 60) post booster dose.

| End point values | Nimenrix Group Y5 | Meningitec Group Y5 | | |
|-----------------------------|-------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 239 | 47 | | |
| Units: Subjects | | | | |
| Any SAE(s) M60 | 0 | 0 | | |

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 8-day period (Days 0-7) after booster vaccination.

Unsolicited symptoms: during the 31-day period (Days 0-30) after booster vaccination.

SAEs: during the 31-day period (Days 0-30) following vaccination

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

Reporting groups

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

Reporting group description: -

| | |
|-----------------------|------------------|
| Reporting group title | Meningitec Group |
|-----------------------|------------------|

Reporting group description: -

| Serious adverse events | Nimenrix Group | Meningitec Group | |
|--|-----------------|------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 273 (0.73%) | 0 / 47 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Limb injury | | | |
| subjects affected / exposed | 1 / 273 (0.37%) | 0 / 47 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Hypersensitivity | | | |
| subjects affected / exposed | 1 / 273 (0.37%) | 0 / 47 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Nimenrix Group | Meningitec Group | |
|---|--------------------|------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 149 / 273 (54.58%) | 23 / 47 (48.94%) | |
| General disorders and administration site conditions | | | |
| Pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 149 / 273 (54.58%) | 23 / 47 (48.94%) | |
| occurrences (all) | 149 | 23 | |
| Redness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 90 / 273 (32.97%) | 17 / 47 (36.17%) | |
| occurrences (all) | 90 | 17 | |
| Swelling | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 70 / 273 (25.64%) | 11 / 47 (23.40%) | |
| occurrences (all) | 70 | 11 | |
| Drowsiness | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 41 / 273 (15.02%) | 10 / 47 (21.28%) | |
| occurrences (all) | 41 | 10 | |
| Irritability | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 40 / 273 (14.65%) | 11 / 47 (23.40%) | |
| occurrences (all) | 40 | 11 | |
| Loss of appetite | | | |
| subjects affected / exposed | 31 / 273 (11.36%) | 8 / 47 (17.02%) | |
| occurrences (all) | 31 | 8 | |
| Temperature (Orally) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 16 / 273 (5.86%) | 1 / 47 (2.13%) | |
| occurrences (all) | 16 | 1 | |
| Pyrexia | | | |
| subjects affected / exposed | 7 / 273 (2.56%) | 3 / 47 (6.38%) | |
| occurrences (all) | 7 | 3 | |
| Headache | | | |

| | | | |
|--|------------------------|---------------------|--|
| subjects affected / exposed occurrences (all) | 5 / 273 (1.83%) 5 | 3 / 47 (6.38%) 3 | |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 15 / 273 (5.49%) 15 | 2 / 47 (4.26%) 2 | |
| Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all) | 15 / 273 (5.49%) 15 | 2 / 47 (4.26%) 2 | |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 13 / 273 (4.76%) 13 | 1 / 47 (2.13%) 1 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 07 April 2010 | <ul style="list-style-type: none">At the time of writing of protocol MenACWY-TT-048 EXT: 039 Y2, 3, 4, 5 (112036) it was decided to test a subset of 75% of the enrolled subjects at each time point for hSBA. This was in accordance with what was initially decided for hSBA testing in the primary study MenACWY-TT-039 (109670). However, later on, it was decided to perform hSBA testing on the blood samples taken 42 days after Visit 1 in study MenACWY-TT-039 (109670) of the subjects vaccinated with MenACWY-TT (alone or co-administered with Priorix-Tetra) or Meningitec at Visit 1. Protocol MenACWY-TT-048 EXT: 039 Y2, 3, 4, 5 (112036) is amended to have the same subset of subjects tested for hSBA in this follow-up study. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported