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	v2
This version publication date	12 August 2016
First version publication date	13 June 2015
Version creation reason	• Correction of full data set Data (typos) were corrected

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)	EMEA-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 ≥ 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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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, vaccination administered in the 109670 study. Subjects are boosted with one dose of Nimenrix™ four years after the primary vaccination.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study.

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. Vaccination administered in the 109670 study. Subjects are boosted with one dose of Priorix-Tetra™ four years after the 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	47
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) titres ≥ 1:8.

End point title	Number of subjects with serum bactericidal assay/activity against Neisseria meningitidis serogroup A, C, W-135 and Y (using baby rabbit complement) titres ≥ 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 titres ≥ 1:8.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:8.[2]

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the rSBA were presents at Month 24 timepoints tested at the GSK laboratory, while the other endpoints presents only the Year 3 timepoint tested at the HPA laboratory.

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 [M24] (N=228; 38)	224	32		
rSBA-MenC [M24] (N=235; 39)	210	28		
rSBA-MenW-135 [M24] (N=236; 39)	232	22		
rSBA-MenY [M24] (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 titres ≥ 1:8.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:8.[3]

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3 and Year 4, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different time-points, the rSBA were presented at Month 24 time-points tested at the GSK laboratory for the Month 48 cohort, while the other endpoints presents only the Year 3 and Year 4 time-points tested at the HPA laboratory.

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 [M24] (N=188; 35)	185	29		
rSBA-MenC [M24] (N=194; 36)	175	24		
rSBA-MenW-135 [M24] (N=194; 36)	192	22		
rSBA-MenY [M24] (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 titres ≥ 1:8.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 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 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 titres ≥ 1:8.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 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 vaccination 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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:128.

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the rSBA were presented at Month 24 timepoints tested at the GSK laboratory, while the other endpoints presents only the Year 3 timepoint tested at the HPA laboratory.

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 [M24] (N=228; 38)	207	23		
rSBA-MenC [M24] (N=235; 39)	115	19		
rSBA-MenW-135 [M24] (N=236; 39)	211	16		
rSBA-MenY [M24] (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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-

	135 and rSBA-MenY titres ≥ 1:128.

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3 and Year 4, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the rSBA were presented at Month 24 timepoints tested at the GSK laboratory for the Month 48 cohort, while the other endpoints presents only the Year 3 and Year4 timepoint tested at the HPA laboratory.

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 [M24] (N=188; 35)	175	22		
rSBA-MenC [M24] (N=194; 36)	97	18		
rSBA-MenW-135 [M24] (N=194; 36)	177	17		
rSBA-MenY [M24] (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 titres.

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

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 titres.

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

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the rSBA were presented at Month 24 timepoints tested at the GSK laboratory, while the other endpoints presents only the Year 3 timepoint tested at the HPA laboratory.

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 [M24] (N=228; 38)	415.3 (360.9 to 478)	102.3 (59.6 to 175.4)		
rSBA-MenC [M24] (N=235; 39)	104.2 (84.7 to 128.2)	58.5 (31.7 to 107.9)		
rSBA-MenW-135 [M24] (N=236; 39)	372.4 (323.4 to 428.9)	39.7 (19.5 to 80.5)		
rSBA-MenY [M24] (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 titres.

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

End point description:

Note: The rSBA have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3 and Year 4, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the rSBA were presented at Month 24

timepoints tested at the GSK laboratory for the Month 48 cohort, while the other endpoints presents only the Year 3 and Year4 timepoint tested at the HPA laboratory.

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 [M24] (N=188; 35)	437.1 (376.6 to 507.4)	106.4 (58.8 to 192.4)		
rSBA-MenC [M24] (N=194; 36)	105.4 (84.6 to 131.3)	53.6 (27.1 to 105.8)		
rSBA-MenW-135 [M24] (N=194; 36)	398.2 (343.1 to 462.1)	49.1 (23.5 to 102.5)		
rSBA-MenY [M24] (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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 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 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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 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 vaccination 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 titres.

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

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 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 titres.

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

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 vaccination 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) titres ≥ 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) titres ≥ 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], ≥ 1:4 (N=183; 23)	46	2		
hSBA-MenA [M24], ≥ 1:8 (N=183; 23)	42	0		
hSBA-MenC [M24], ≥ 1:4 (N=175; 19)	154	11		
hSBA-MenC [M24], ≥ 1:8 (N=175; 19)	152	10		
hSBA-MenW-135 [M24], ≥ 1:4 (N=180; 23)	167	0		
hSBA-MenW-135 [M24], ≥ 1:8 (N=180; 23)	164	0		
hSBA-MenY [M24], ≥ 1:4 (N=154; 22)	134	5		
hSBA-MenY [M24], ≥ 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) titres ≥ 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) titres ≥ 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], ≥ 1:4 (N=251; 31)	95	5		
hSBA-MenA [M36], ≥ 1:8 (N=251; 31)	90	4		
hSBA-MenC [M36], ≥ 1:4 (N=253; 31)	204	13		
hSBA-MenC [M36], ≥ 1:8 (N=253; 31)	198	13		
hSBA-MenW-135 [M36], ≥ 1:4 (N=254; 33)	209	2		
hSBA-MenW-135 [M36], ≥ 1:8 (N=254; 33)	209	2		
hSBA-MenY [M36], ≥ 1:4 (N=250; 33)	184	6		
hSBA-MenY [M36], ≥ 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) titres ≥ 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) titres ≥ 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], ≥ 1:4 (N=198; 28)	58	4		
hSBA-MenA [M48], ≥ 1:8 (N=198; 28)	57	4		
hSBA-MenC [M48], ≥ 1:4 (N=209; 32)	154	15		
hSBA-MenC [M48], ≥ 1:8 (N=209; 32)	153	15		
hSBA-MenW-135 [M48], ≥ 1:4 (N=165; 26)	134	2		
hSBA-MenW-135 [M48], ≥ 1:8 (N=165; 26)	133	2		
hSBA-MenY [M48], ≥ 1:4 (N=130; 27)	85	6		
hSBA-MenY [M48], ≥ 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 titres.

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres.

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 titres.

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres.

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 titres.

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres.

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:

Note: The anti-PS have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the anti-PS were presented at Month 24 timepoints tested at the GSK laboratory, while the other endpoints presents only the Year 3 timepoint tested at the HPA laboratory.

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 [24], ≥ 0.3 (N=114; 21)	61	6		
Anti-PSA [24], ≥ 2.0 (N=114; 21)	10	2		
Anti-PSC [24], ≥ 0.3 (N=111; 20)	28	4		
Anti-PSC [24], ≥ 2.0 (N=111; 20)	0	0		
Anti-PSW-135 [24], ≥ 0.3 (N=106; 20)	68	0		
Anti-PSW-135 [24], ≥ 2.0 (N=106; 20)	11	0		
Anti-PSY [24], ≥ 0.3 (N=110; 21)	89	1		
Anti-PSY [24], ≥ 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:

Note: The anti-PS have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3 and Year 4, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the anti-PS were presented at Month 24 timepoints tested at the GSK laboratory for the Month 48 cohort, while the other endpoints presents only the Year 3 and Year4 timepoint tested at the HPA laboratory.

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 [24], ≥ 0.3 (N=93; 20)	50	5		
Anti-PSA [24], ≥ 2.0 (N=93; 20)	9	2		
Anti-PSC [24], ≥ 0.3 (N=91; 19)	21	3		
Anti-PSC [24], ≥ 2.0 (N=91; 19)	0	0		
Anti-PSW-135 [24], ≥ 0.3 (N=86; 19)	55	0		
Anti-PSW-135 [24], ≥ 2.0 (N=86; 19)	8	0		
Anti-PSY [24], ≥ 0.3 (N=90; 20)	73	1		
Anti-PSY [24], ≥ 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:

Note: The anti-PS have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the anti-PS were presented at Month 24 timepoints tested at the GSK laboratory, while the other endpoints presents only the Year 3 timepoint tested at the HPA laboratory.

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 [24] (N=114; 21)	0.39 (0.32 to 0.48)	0.27 (0.17 to 0.43)		
Anti-PSC [24] (N=111; 20)	0.21 (0.19 to 0.24)	0.19 (0.15 to 0.25)		
Anti-PSW-135 [24] (N=106; 20)	0.48 (0.39 to 0.59)	0.15 (0.15 to 0.15)		
Anti-PSY [24] (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:

Note: The anti-PS have been analysed at a different laboratory (Health Protection Agency or HPA) at Year 3 and Year 4, compared to previous years (GSK). To reflect this difference, which limits direct longitudinal comparison of the results of different timepoints, the anti-PS were presented at Month 24 timepoints tested at the GSK laboratory for the Month 48 cohort, while the other endpoints presents only the Year 3 and Year4 timepoint tested at the HPA laboratory.

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 [24] (N=93; 20)	0.39 (0.31 to 0.5)	0.26 (0.16 to 0.42)		
Anti-PSC [24] (N=91; 19)	0.2 (0.18 to 0.23)	0.19 (0.14 to 0.25)		
Anti-PSW-135 [24] (N=86; 19)	0.46 (0.37 to 0.58)	0.15 (0.15 to 0.15)		
Anti-PSY [24] (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:

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 Month 36 post-primary 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:

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 Month 48 post-primary vaccination 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:

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 Month 36 post-primary 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:

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 Month 48 post-primary vaccination 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: 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 titres above the cut-off values.

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

End point description:

End point type	Secondary

End point timeframe:

At Month 60 pre-primary vaccination and post-primary vaccination

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], ≥ 1:128 (N=106; 22)	24	2		
rSBA-MenA, POST [M60], ≥ 1:8 (N=227; 22)	227	12		
rSBA-MenA, POST [M60], ≥ 1:128 (N=227; 22)	227	7		
rSBA-MenC, PRE [M60], ≥ 1:8 (N=107; 19)	31	6		
rSBA-MenC, PRE [M60], ≥ 1:128 (N=107; 19)	14	1		
rSBA-MenC, POST [M60], ≥ 1:8 (N=226; 46)	226	44		
rSBA-MenC, POST [M60], ≥ 1:128 (N=226; 46)	214	25		
rSBA-MenW-135, PRE [M60], ≥ 1:8 (N=117; 27)	57	14		
rSBA-MenW-135, PRE [M60], ≥ 1:128 (N=117; 27)	25	7		
rSBA-MenW-135, POST [M60], ≥ 1:8 (N=227; 24)	227	15		
rSBA-MenW-135, POST [M60], ≥ 1:128 (N=227; 24)	227	6		
rSBA-MenY, PRE [M60], ≥ 1:8 (N=122; 27)	76	19		
rSBA-MenY, PRE [M60], ≥ 1:128 (N=122; 27)	52	14		
rSBA-MenY, POST [M60], ≥ 1:8 (N=226; 26)	226	26		
rSBA-MenY, POST [M60], ≥ 1:128 (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 titres.

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

End point description:

End point type	Secondary

End point timeframe:

At Month 60 pre-primary vaccination and post-primary vaccination

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 titres above the cut-off values.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres 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], ≥ 1:8 (N=214; 43)	214	9		
rSBA-MenA [M49], ≥ 1:128 (N=214; 43)	214	8		
rSBA-MenC [M49], ≥ 1:8 (N=215; 43)	215	43		

rSBA-MenC [M49], ≥ 1:128 (N=215; 43)	215	43		
rSBA-MenW-135 [M49], ≥ 1:8 (N=215; 43)	215	8		
rSBA-MenW-135 [M49], ≥ 1:128 (N=215; 43)	215	7		
rSBA-MenY [M49], ≥ 1:8 (N=215; 43)	215	14		
rSBA-MenY [M49], ≥ 1:128 (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 titres above the cut-off values.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres 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	231	46		
Units: Subjects				
rSBA-MenA [M60], ≥ 1:8 (N=231; 46)	231	3		
rSBA-MenA [M60], ≥ 1:128 (N=231; 46)	229	3		
rSBA-MenC [M60], ≥ 1:8 (N=231; 46)	225	45		
rSBA-MenC [M60], ≥ 1:128 (N=231; 46)	181	40		
rSBA-MenW-135 [M60], ≥ 1:8 (N=231; 46)	231	2		
rSBA-MenW-135 [M60], ≥ 1:128 (N=231; 46)	229	2		
rSBA-MenY [M60], ≥ 1:8 (N=231; 46)	231	11		
rSBA-MenY [M60], ≥ 1:128 (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 titres.	
End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres.

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

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=231; 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 titres above the cut-off values.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres 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], ≥ 1:4 (N=202; 28)	201	4		
hSBA-MenA [M49], ≥ 1:8 (N=202; 28)	201	4		
hSBA-MenC [M49], ≥ 1:4 (N=209; 33)	209	33		
hSBA-MenC [M49], ≥ 1:8 (N=209; 33)	209	33		
hSBA-MenW-135 [M49], ≥ 1:4 (N=192; 25)	192	1		
hSBA-MenW-135 [M49], ≥ 1:8 (N=192; 25)	192	1		
hSBA-MenY [M49], ≥ 1:4 (N=173; 25)	173	6		
hSBA-MenY [M49], ≥ 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 titres above the cut-off values.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres 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], ≥ 1:4 (N=221; 28)	211	3		
hSBA-MenA [M60], ≥ 1:8 (N=221; 28)	211	3		
hSBA-MenC [M60], ≥ 1:4 (N=228; 33)	228	33		
hSBA-MenC [M60], ≥ 1:8 (N=228; 33)	228	33		
hSBA-MenW-135 [M60], ≥ 1:4 (N=218; 31)	218	5		
hSBA-MenW-135 [M60], ≥ 1:8 (N=218; 31)	218	5		
hSBA-MenY [M60], ≥ 1:4 (N=206; 31)	206	10		
hSBA-MenY [M60], ≥ 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 titres.

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres.

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 titres.

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres.

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: Titres				
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: µg/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 the 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 (N=244;47)	41	10		
Any irritability (N=243;47)	40	11		
Any loss of appetite (N=243;47)	31	8		
Any temperature (orally, ≥ 37.5°C) (N=243;47)	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 serious adverse events (SAEs).

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

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

End point description:

End point type	Secondary

End point timeframe:

At Month 36

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 serious adverse events (SAEs).

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

End point description:

End point type	Secondary

End point timeframe:

At Month 48

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 serious adverse events (SAEs).

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

End point title	Number of subjects reporting any serious 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.

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and it is encoded as equal to the number of subjects affected.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Meningitec Group

Reporting group description: -

Reporting group title	Nimenrix Group

Reporting group description: -

Serious adverse events	Meningitec Group	Nimenrix Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	2 / 245 (0.82%)	
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	0 / 48 (0.00%)	1 / 245 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Hypersensitivity			
subjects affected / exposed	0 / 48 (0.00%)	1 / 245 (0.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Meningitec Group	Nimenrix Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 48 (47.92%)	149 / 245 (60.82%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed[1]	23 / 47 (48.94%)	149 / 244 (61.07%)	
occurrences (all)	23	149	
Redness			
subjects affected / exposed[2]	17 / 47 (36.17%)	90 / 244 (36.89%)	
occurrences (all)	17	90	
Swelling			
subjects affected / exposed[3]	11 / 47 (23.40%)	70 / 244 (28.69%)	
occurrences (all)	11	70	
Drowsiness			
subjects affected / exposed[4]	10 / 47 (21.28%)	41 / 244 (16.80%)	
occurrences (all)	10	41	
Irritability			
subjects affected / exposed[5]	11 / 47 (23.40%)	40 / 243 (16.46%)	
occurrences (all)	11	40	
Loss of appetite			
subjects affected / exposed[6]	8 / 47 (17.02%)	31 / 243 (12.76%)	
occurrences (all)	8	31	
Temperature (Orally)			
subjects affected / exposed[7]	1 / 47 (2.13%)	16 / 243 (6.58%)	
occurrences (all)	1	16	
Pyrexia			
subjects affected / exposed	3 / 48 (6.25%)	7 / 245 (2.86%)	
occurrences (all)	3	7	
Headache			
subjects affected / exposed	3 / 48 (6.25%)	5 / 245 (2.04%)	
occurrences (all)	3	5	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 48 (4.17%)	15 / 245 (6.12%)	
occurrences (all)	2	15	
Infections and infestations			

Upper respiratory tract infection			
subjects affected / exposed	2 / 48 (4.17%)	15 / 245 (6.12%)	
occurrences (all)	2	15	
Nasopharyngitis			
subjects affected / exposed	1 / 48 (2.08%)	13 / 245 (5.31%)	
occurrences (all)	1	13	

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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 April 2010	• 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