

**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	09 September 2012

Results information

Result version number	v3 (current)
This version publication date	08 March 2023
First version publication date	13 June 2015
Version creation reason	

Trial information**Trial identification**

Sponsor protocol code	112036
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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	No

1901/2006 apply to this trial?	
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	30 May 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 December 2009
Global end of trial reached?	Yes
Global end of trial date	09 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 greater than or equal to (\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	24 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	0

wk	
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:

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

Pre-assignment

Screening details:

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
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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
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Arm title	Nimenrix Group Y2
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Arm description:

Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.

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
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Arm description:

Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266]

(Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.

Arm type	Active comparator
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.

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.

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: The number of subjects reported in the baseline period are number vaccinated, as compared to worldwide number enrolled in the trial.

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:

Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.

Arm type	Experimental
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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.

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.

Arm title	Meningitec Group Y3
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Arm description:

Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.

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:	
Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
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:	
Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Arm type	Active comparator
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.	
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.

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 48- 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:

Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.

Arm type	Experimental
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.

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.

Arm title	Meningitec Group Booster (Month 49)
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Arm description:

Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.

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
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Arm title	Nimenrix Group Y5
Arm description: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
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: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Arm type	Active comparator
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.	
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.	

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
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Reporting group description:

Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.

Reporting group title	Meningitec Group Y2
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Reporting group description:

Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.

Reporting group values	Nimenrix Group Y2	Meningitec Group Y2	Total
Number of subjects	253	42	295
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	253	42	295
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	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: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
Reporting group title	Meningitec Group Y2
Reporting group description: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Reporting group title	Nimenrix Group Y3
Reporting group description: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
Reporting group title	Meningitec Group Y3
Reporting group description: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Reporting group title	Nimenrix Group Y4
Reporting group description: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
Reporting group title	Meningitec Group Y4
Reporting group description: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Reporting group title	Nimenrix Group Booster (Month 49)
Reporting group description: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
Reporting group title	Meningitec Group Booster (Month 49)
Reporting group description: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	
Reporting group title	Nimenrix Group Y5
Reporting group description: Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.	
Reporting group title	Meningitec Group Y5
Reporting group description: Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.	

Primary: Number of subjects with serum bactericidal assay/activity (rSBA) against Neisseria meningitidis serogroup A, C, W-135 and Y (using baby rabbit complement) titres \geq the cut-off

End point title	Number of subjects with serum bactericidal assay/activity (rSBA) against Neisseria meningitidis serogroup A, C, W-135 and Y (using baby rabbit complement) titres \geq the cut-off ^[1]
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End point description:

The cut-off value for the assay was greater than or equal to (\geq) 1:8, as measured at the GlaxoSmithKline (GSK) laboratory.

End point type	Primary
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End point timeframe:

At Month 24 post primary vaccination

Notes:

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

Justification: The scope of this endpoint was descriptive analysis.

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 \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off ^[2]
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End point description:

The cut-off value for the assay was \geq 1:8. The analysis of this endpoint was performed by GSK.

End point type	Primary
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End point timeframe:

At Month 36 post primary vaccination

Notes:

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

Justification: The scope of this endpoint was descriptive analysis.

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 titres \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off ^[3]
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End point description:

The cut-off value for the assay was $\geq 1:8$. The analysis of this endpoint was performed by GSK.

End point type	Primary
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End point timeframe:

At Month 48 post primary vaccination

Notes:

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

Justification: The scope of this endpoint was descriptive analysis.

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 titres

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ^[4]
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End point description:

The cut-off value for the assay was $\geq 1:8$. The rSBA-MenA results for the Year 3 time point were obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Primary
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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 scope of this endpoint was descriptive analysis.

End point values	Nimenrix Group Y3	Meningitec Group Y3		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	262 ^[5]	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		

Notes:

[5] - Number of subjects analyzed is greater due to addition of subjects after they started the arm

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

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ^[6]
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End point description:

The cut-off value for the assay was $\geq 1:8$. The rSBA-MenA results for the Year 4 time point were obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Primary
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End point timeframe:

At Month 48 post-primary vaccination

Notes:

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

Justification: The scope of this endpoint was descriptive analysis.

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 \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off
End point description:	The cut-off value for the assay was \geq 1:128, as measured at the GlaxoSmithKline (GSK) laboratory.
End point type	Secondary
End point timeframe:	At Month 24 post primary vaccination

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 \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off
End point description:	The cut-off value for the assay was \geq 1:128. The analysis of this endpoint was performed by GSK.
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	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 titres \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off
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End point description:

The cut-off value for the assay was $\geq 1:128$. The analysis of this endpoint was performed by GSK.

End point type	Secondary
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End point timeframe:

At Month 48 post primary vaccination

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 titres

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

The results for the assay were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres, as measured at the GlaxoSmithKline (GSK) laboratory.

End point type	Secondary
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End point timeframe:

At Month 24 post primary vaccination

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:	Results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres. The analysis of this endpoint was performed by GSK.
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	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 titres

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

Results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres. The analysis of this endpoint was performed by GSK.

End point type	Secondary
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End point timeframe:

At Month 48 post primary vaccination

End point values	Nimenrix Group Y4	Meningitec Group Y4		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	195	37		
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 titres \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off
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End point description:

The cut-off for the assay was $\geq 1:128$. rSBA-MenA, MenC, MenW-135 and MenY results for the Year 3 time point obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Secondary
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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 \geq the cut-off

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres \geq the cut-off
End point description:	The cut-off for the assay was \geq 1:128. rSBA-MenA, MenC, MenW-135, MenY results for the Year 4 time point 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

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:	Results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres. rSBA-MenA, MenC, MenW and MenY results for the Year 3 time point 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:	
Results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres. rSBA-MenA, MenC, MenW and MenY results for the Year 4 time point 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	

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)		
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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 \geq the cut-off

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) titres \geq the cut-off
End point description:	The cut-off values for the assay were \geq 1:4 and 1:8, respectively. The analysis of this endpoint was performed by GSK.
End point type	Secondary
End point timeframe:	At Month 24 post primary vaccination

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) titres \geq the cut-off

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) titres \geq the cut-off
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End point description:

The cut-off for the assay were $\geq 1:4$ and $1:8$. The analysis of this endpoint was performed by GSK.

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	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) titres \geq the cut-off

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 \geq the cut-off

End point description:

The cut-off for the assay were $\geq 1:4$ and $1:8$, as assessed by the GSK laboratory.

End point type Secondary

End point timeframe:

At Month 48 post primary vaccination

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 titres

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

The results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres, as assessed by the GSK laboratory.

End point type	Secondary
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End point timeframe:

At Month 24 post primary vaccination

End point values	Nimenrix Group Y2	Meningitec Group Y2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	183	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
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End point description:

The results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres, as assessed by the GSK laboratory.

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	254	33		
Units: Titres				
geometric mean (confidence interval 95%)				
hSBA-MenA [M36] (N=31, 251)	5.8 (4.8 to 7)	2.6 (2.1 to 3.3)		
hSBA-MenC [M36] (N=31, 253)	37.8 (29.4 to 48.6)	6.2 (3.7 to 10.3)		
hSBA-MenW-135 [M36] (N=33, 254)	52 (41.4 to 65.2)	2.4 (1.8 to 3.1)		
hSBA-MenY [M36] (N=33, 250)	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:	
The results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres, as measured by GSK.	
End point type	Secondary
End point timeframe:	
At Month 48 post primary vaccination	

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 \geq the cut-off values

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
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End point description:

The cut-off values for the assay were ≥ 0.3 microgram per milliliter ($\mu\text{g}/\text{mL}$) and ≥ 2.0 $\mu\text{g}/\text{mL}$, respectively, as measured at the GlaxoSmithKline (GSK) laboratory.

End point type	Secondary
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End point timeframe:

At Month 24 post primary vaccination

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 \geq the cut-off values

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
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End point description:

The cut-off values for the assay were ≥ 0.3 $\mu\text{g}/\text{mL}$ and ≥ 2.0 $\mu\text{g}/\text{mL}$, respectively, as measured by the GSK laboratory.

End point type	Secondary
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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	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 \geq the cut-off values

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
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End point description:

The cut-off values for the assay were ≥ 0.3 $\mu\text{g/mL}$ and ≥ 2.0 $\mu\text{g/mL}$, respectively, as measured by GSK.

End point type	Secondary
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End point timeframe:

At Month 48 post primary vaccination

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
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End point description:

The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in µg/mL, as measured at the GlaxoSmithKline (GSK) laboratory.

End point type	Secondary
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End point timeframe:

At Month 24 post primary vaccination

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
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End point description:

The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in µg/mL, as measured by GSK.

End point type	Secondary
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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	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:	The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in µg/mL, as measured by GSK.
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 \geq the cut-off values

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
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End point description:

The cut-off values for the assay were $\geq 0.3 \mu\text{g/mL}$ and $\geq 0.2 \mu\text{g/mL}$. Anti-PS results for the Year 3 time point were obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Secondary
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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 \geq the cut-off values

End point title	Number of subjects with Anti-polysaccharide A (anti-PSA), anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
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End point description:

The cut-off values for the assay were $\geq 0.3 \mu\text{g/mL}$ and $\geq 2.0 \mu\text{g/mL}$, respectively. Anti-PS results for the Year 4 time point were obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Secondary
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End point timeframe:

At Month 48 post-primary 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
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End point description:

The results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in $\mu\text{g/mL}$. Anti-PS results for the Year 3 time point were obtained by re-testing the samples in parallel at Public Health England (PHE). Results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in $\mu\text{g/mL}$.

End point type	Secondary
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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: $\mu\text{g/mL}$				
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)		
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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
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End point description:

The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in µg/mL. Anti-PS results for the Year 4 time point obtained by re-testing the samples in parallel at Public Health England (PHE).

End point type	Secondary
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End point timeframe:

At Month 48 post-primary 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 ≥ the cut-off values

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

The cut-off values for the assay were 1:8 and 1:128, as measured by the PHE laboratory.

End point type	Secondary
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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], $\geq 1:128$ (N=214; 43)	214	8		
rSBA-MenC [M49], $\geq 1:8$ (N=215; 43)	215	43		
rSBA-MenC [M49], $\geq 1:128$ (N=215; 43)	215	43		
rSBA-MenW-135 [M49], $\geq 1:8$ (N=215; 43)	215	8		
rSBA-MenW-135 [M49], $\geq 1:128$ (N=215; 43)	215	7		
rSBA-MenY [M49], $\geq 1:8$ (N=215; 43)	215	14		
rSBA-MenY [M49], $\geq 1:128$ (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 \geq the cut-off values

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

The cut off values for the assay were 1:8 and 1:128, as measured by the PHE laboratory.

End point type	Secondary
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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], $\geq 1:8$ (N=231; 46)	231	3		
rSBA-MenA [M60], $\geq 1:128$ (N=231; 46)	229	3		
rSBA-MenC [M60], $\geq 1:8$ (N=231; 46)	225	45		

rSBA-MenC [M60], $\geq 1:128$ (N=231; 46)	181	40		
rSBA-MenW-135 [M60], $\geq 1:8$ (N=231; 46)	231	2		
rSBA-MenW-135 [M60], $\geq 1:128$ (N=231; 46)	229	2		
rSBA-MenY [M60], $\geq 1:8$ (N=231; 46)	231	11		
rSBA-MenY [M60], $\geq 1:128$ (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
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End point description:

Results were tabulated as geometric mean antibody titre calculated on all subjects, expressed in titres, as measured by the PHE laboratory.

End point type	Secondary
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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
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End point description:

Results were tabulated as geometric mean antibody titre (GMT) calculated on all subjects, as measured by the PHE laboratory.

End point type	Secondary
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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 \geq the cut-off values

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres \geq the cut-off values
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End point description:

The cut off values for the assay were \geq 1:4 and \geq 1:8 respectively, as measured by GSK.

End point type	Secondary
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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=28, 202)	201	4		
hSBA-MenA [M49], $\geq 1:8$ (N=28, 202)	201	4		
hSBA-MenC [M49], $\geq 1:4$ (N=33, 209)	209	33		
hSBA-MenC [M49], $\geq 1:8$ (N=33, 209)	209	33		
hSBA-MenW-135 [M49], $\geq 1:4$ (N=25,192)	192	1		
hSBA-MenW-135 [M49], $\geq 1:8$ (N=25,192)	192	1		
hSBA-MenY [M49], $\geq 1:4$ (N=25,173)	173	6		
hSBA-MenY [M49], $\geq 1:8$ (N=25,173)	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 \geq the cut-off values

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY titres \geq the cut-off values
End point description:	The cut off values for the assay were $\geq 1:4$ and $\geq 1:8$, respectively, as measured by GSK.
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 titres

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

The results were tabulated as geometric mean antibody titre (GMT) calculated on all subjects, expressed in titres, as measured by GSK.

End point type	Secondary
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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
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End point description:

The results were tabulated as geometric mean antibody titre (GMT) calculated on all subjects, expressed

in titres, as measured by GSK.

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 ≥ the cut-off values

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY ≥ the cut-off values
End point description:	
The cut-off values for the assay were 0.3 µg/mL and 2.0 µg/mL, as measured by the PHE laboratory.	
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 \geq the cut-off values

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW, and anti-PSY \geq the cut-off values
End point description:	The cut-off for the assay were 0.3 $\mu\text{g/mL}$ and 2.0 $\mu\text{g/mL}$, as measured by the PHE laboratory.
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:	The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in $\mu\text{g/mL}$, as measured by the PHE laboratory.
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:	The results were tabulated as geometric mean antibody concentration calculated on all subjects, expressed in µg/mL, as measured by the PHE laboratory.
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)		
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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
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End point description:

Solicited local symptoms assessed were pain, redness and swelling. Any was defined as occurrence of any local symptom regardless of intensity grade.

End point type	Secondary
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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
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End point description:

Solicited general symptoms assessed were drowsiness, irritability, loss of appetite, temperature (measured orally). Any was defined as occurrence of any general symptoms, regardless of their intensity grade or their relationship to vaccination.

End point type	Secondary
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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, $\geq 37.5^{\circ}\text{C}$) (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:	
Any was defined as the occurrence of any adverse event regardless of intensity grade or relation to vaccination. An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.	
End point type	Secondary
End point timeframe:	
During the 31-day 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:	
Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.	

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

End point timeframe:

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:

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

End point type | Secondary

End point timeframe:

From month 48 to month 49 (post booster follow up period)

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:

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

End point type | Secondary

End point timeframe:
From month 49 to month 60

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 solicited local and general symptoms were only collected for those subjects who filled-in their symptom sheets.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Nimenrix Group
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Reporting group description:

Subjects vaccinated with Nimenrix vaccine in the primary study 109670 [NCT00474266] (Nimenrix+ Priorix-Tetra Group and Nimenrix Group) and and who at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study.

Reporting group title	Meningitec Group
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Reporting group description:

Subjects who received Meningitec vaccine in the primary vaccination study 109670 [NCT00474266] (Priorix-Tetra Group and Meningitec Group) and at Year 4 received a booster dose with the same meningococcal vaccine as given in the primary study, as the only treatment administered after the primary study.

Serious adverse events	Nimenrix Group	Meningitec Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 245 (0.82%)	0 / 48 (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 / 245 (0.41%)	0 / 48 (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 / 245 (0.41%)	0 / 48 (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	190 / 245 (77.55%)	39 / 48 (81.25%)	
Nervous system disorders			
Headache			
subjects affected / exposed	5 / 245 (2.04%)	3 / 48 (6.25%)	
occurrences (all)	6	4	
Somnolence			
subjects affected / exposed	41 / 245 (16.73%)	10 / 48 (20.83%)	
occurrences (all)	41	10	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	149 / 245 (60.82%)	23 / 48 (47.92%)	
occurrences (all)	149	23	
Pyrexia			
subjects affected / exposed	23 / 245 (9.39%)	4 / 48 (8.33%)	
occurrences (all)	23	4	
Swelling			
subjects affected / exposed	70 / 245 (28.57%)	11 / 48 (22.92%)	
occurrences (all)	70	11	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	15 / 245 (6.12%)	2 / 48 (4.17%)	
occurrences (all)	15	2	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	90 / 245 (36.73%)	17 / 48 (35.42%)	
occurrences (all)	90	17	
Psychiatric disorders			
Irritability			
subjects affected / exposed	40 / 245 (16.33%)	11 / 48 (22.92%)	
occurrences (all)	40	11	
Infections and infestations			

Nasopharyngitis subjects affected / exposed occurrences (all)	13 / 245 (5.31%) 14	1 / 48 (2.08%) 1	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	15 / 245 (6.12%) 15	2 / 48 (4.17%) 2	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	31 / 245 (12.65%) 31	8 / 48 (16.67%) 8	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 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