Clinical trial results:
A phase IIb, open, randomized, controlled primary vaccination study to evaluate the non-inferiority and the persistence of the immune response of GSK Biologicals' meningococcal serogroup ACWY conjugate vaccine given intramuscularly versus Meningitec™ or Mencevax™ ACWY to healthy subjects aged 1 through 10 years of age.

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2006-004236-70
Trial protocol	FI
Global end of trial date	24 May 2012

Results information

Result version number	v2
This version publication date	11 June 2016
First version publication date	17 June 2015
Version creation reason	• Correction of full data set Data correction due to a system error in EudraCT – Results

Trial information

Trial identification

Sponsor protocol code	108658-60-61-63-65-68

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00427908
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 May 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 May 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

One month after vaccination:

For Subjects of 2 years of age and above
•To evaluate the non-inferiority of MenACWY-TT conjugate vaccine compared to MenACWY plain polysaccharide vaccine in terms of the vaccine response$ to MenA, MenC, MenY, and MenW-135.

For Subjects below 2 years of age
•To evaluate the non-inferiority of the vaccine response induced by MenACWY-TT conjugate vaccine when compared to the licensed MenC-CRM vaccine for MenC as measured by rSBA.
•To evaluate the immunogenicity induced by MenACWY-TT conjugate vaccine for MenA, MenW-135, and MenY as measured by rSBA.

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	07 February 2007
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: 613
Worldwide total number of subjects	613
EEA total number of subjects	613

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)	304
Children (2-11 years)	309
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.

Period 1

Period 1 title	Primary phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix™ 1-2 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region.

Arm title	Nimenrix™ 2-6 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region.

Arm title	Nimenrix™ 6-11 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region.

Arm title	Meningitec™ 1-2 years of age Group

Arm description: -

Arm type	Active comparator

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region.

Arm title	Mencevax™ 2-6 years of age Group

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Arm title	Mencevax™ 6-11 years of age Group

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 1	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-6 years of age Group	Nimenrix™ 6-11 years of age Group
Started	229	114	117
Completed	224	110	112
Not completed	5	4	5
Consent withdrawn by subject	1	3	-
Lost to follow-up (complete vaccination)	4	1	-
Lost to follow-up (completed vaccination)	-	-	5

Number of subjects in period 1	Meningitec™ 1-2 years of age Group	Mencevax™ 2-6 years of age Group	Mencevax™ 6-11 years of age Group
Started	75	39	39
Completed	72	39	39
Not completed	3	0	0
Consent withdrawn by subject	1	-	-
Lost to follow-up (complete vaccination)	2	-	-
Lost to follow-up (completed vaccination)	-	-	-

Period 2	
Period 2 title	Persistence Phase Year 1
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	Yes
Arm title	Nimenrix™ 1-2 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: One dose administered intramuscularly in the non-dominant deltoid or thigh region.	
Arm title	Nimenrix™ 2-11 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: One dose administered intramuscularly in the non-dominant deltoid or thigh region	
Arm title	Meningitec™ 1-2 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: One dose administered intramuscularly in the non-dominant deltoid or thigh region	
Arm title	Mencevax™ 2-11 years of age Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 2[1]	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Started	222	221	71
Completed	222	221	71

Number of subjects in period 2[1]	Mencevax™ 2-11 years of age Group
Started	78
Completed	78

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all study participants returned in time for every study visit, but they were allowed to continue the study nonetheless. The number of participants who started each study period depends on the actual rate of return of the subjects.

Period 3

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix™ 1-2 years of age Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Nimenrix™ 2-11 years of age Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Meningitec™ 1-2 years of age Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Mencevax™ 2-11 years of age Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 3[2]	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Started	208	215	53
Completed	208	215	53

Number of subjects in period 3[2]	Mencevax™ 2-11 years of age Group
Started	61
Completed	61

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix™ 1-2 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Nimenrix™ 2-11 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Meningitec™ 1-2 years of age Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Mencevax™ 2-11 years of age Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Number of subjects in period 4[3]	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Started	185	201	38
Completed	185	201	38

Number of subjects in period 4[3]	Mencevax™ 2-11 years of age Group
Started	38
Completed	38

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	Persistence Phase Year 4
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix™ 1-2 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Nimenrix™ 2-11 years of age Group

Arm description: -

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

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Meningitec™ 1-2 years of age Group

Arm description: -

Arm type	Experimental

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Mencevax™ 2-11 years of age Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 5[4]	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Started	165	192	34
Completed	165	192	34

Number of subjects in period 5[4]	Mencevax™ 2-11 years of age Group
Started	32
Completed	32

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.

Period 6

Period 6 title	Persistence Phase Year 5
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Nimenrix™ 1-2 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Nimenrix™ 2-11 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	MenACWY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Meningitec™ 1-2 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	MenC-CRM
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered intramuscularly in the non-dominant deltoid or thigh region

Arm title	Mencevax™ 2-11 years of age Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Mencevax™
Investigational medicinal product code	
Other name	MenACWY
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 6[5]	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Started	52	99	12
Completed	52	99	12

Number of subjects in period 6[5]	Mencevax™ 2-11 years of age Group
Started	13
Completed	13

Notes:

[5] - 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™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-6 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 6-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-6 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 6-11 years of age Group
Reporting group description: -	

Reporting group values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-6 years of age Group	Nimenrix™ 6-11 years of age Group
Number of subjects	229	114	117
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: months			
arithmetic mean	19.1	44.1	99
standard deviation	± 2.96	± 12.97	± 16.27
Gender categorical Units: Subjects			
Female	116	60	55
Male	113	54	62

Reporting group values	Meningitec™ 1-2 years of age Group	Mencevax™ 2-6 years of age Group	Mencevax™ 6-11 years of age Group
Number of subjects	75	39	39
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days)			

Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: months			
arithmetic mean	19.3	44.8	98.3
standard deviation	± 3.07	± 12.51	± 15.06
Gender categorical Units: Subjects			
Female	39	18	19
Male	36	21	20

Reporting group values	Total		
Number of subjects	613		
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			
standard deviation	-		
Gender categorical Units: Subjects			
Female	307		
Male	306		

Subject analysis sets	
Subject analysis set title	Nimenrix™ 2-11 years of age Primary Phase Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pooled group of subjects above 2 years of age, participating in the Primary Phase.	
Subject analysis set title	Mencevax™ 2-11 years of age Primary Phase Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pooled group of subjects above 2 years of age, participating in the Primary phase.	

Reporting group values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group	
Number of subjects	231	78	
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: months			
arithmetic mean	71.91	71.55	
standard deviation	± 31.19	± 30.23	
Gender categorical Units: Subjects			
Female	115	37	
Male	116	41	

End points

End points reporting groups

Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-6 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 6-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-6 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 6-11 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group

Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	
Subject analysis set title	Nimenrix™ 2-11 years of age Primary Phase Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pooled group of subjects above 2 years of age, participating in the Primary Phase.	
Subject analysis set title	Mencevax™ 2-11 years of age Primary Phase Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Pooled group of subjects above 2 years of age, participating in the Primary phase.	

Primary: Number of subjects with rSBA antibodies vaccine response

End point title	Number of subjects with rSBA antibodies vaccine response
End point description:	
End point type	Primary
End point timeframe: One Month after vaccination	

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	219	70		
Units: Subjects				
rSBA-MenA [N= 185;62]	182	57		
rSBA-MenC [N= 212;69]	200	56		
rSBA-MenW-135 [N= 199;68]	199	65		
rSBA-MenY [N=219;70]	217	58		

Statistical analyses

Statistical analysis title	Difference in VRR to rSBA-MenA

Statistical analysis description:

To evaluate the non-inferiority of MenACWY-TT conjugate vaccine compared to MenACWY plain polysaccharide vaccine in terms of the vaccine response (VRR) to MenA. Response to a vaccine antigen component was defined as:
- For initially seronegative subject, post-vaccination serum bactericidal assay using rabbit complement (rSBA) titer ≥ 1:32;
- For initially seropositive subject, at least 4-fold increase in rSBA titer from pre- to post-vaccination.

Comparison groups	Nimenrix™ 2-11 years of age Primary Phase Group v Mencevax™ 2-11 years of age Primary Phase Group

Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference in percentage
Point estimate	6.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	16.04

Notes:

[1] - Criterion indicative of non-inferiority: lower limit of the standardized asymptotic 95% confidence interval (CI) for the group difference (MenACWY-TT minus MenACWY) in the percentage of subjects with bactericidal vaccine response to be greater than or equal to -15% for each of the four antigens.

Statistical analysis title	Difference in VRR to rSBA-MenC

Statistical analysis description:

To evaluate the non-inferiority of MenACWY-TT conjugate vaccine compared to MenACWY plain polysaccharide vaccine in terms of the vaccine response (VRR) to MenC. Response to a vaccine antigen component was defined as:
- For initially seronegative subject, post-vaccination serum bactericidal assay using rabbit complement (rSBA) titer ≥ 1:32;
- For initially seropositive subject, at least 4-fold increase in rSBA titer from pre- to post-vaccination.

Comparison groups	Mencevax™ 2-11 years of age Primary Phase Group v Nimenrix™ 2-11 years of age Primary Phase Group
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in percentage
Point estimate	13.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.79
upper limit	24.32

Notes:

[2] - Criterion indicative of non-inferiority: lower limit of the standardized asymptotic 95% confidence interval (CI) for the group difference (MenACWY-TT minus MenACWY) in the percentage of subjects with bactericidal vaccine response is greater than or equal to -15% for each of the four antigens.

Statistical analysis title	Difference in VRR to rSBA-MenW-135

Statistical analysis description:

To evaluate the non-inferiority of MenACWY-TT conjugate vaccine compared to MenACWY plain polysaccharide vaccine in terms of the vaccine response to MenW-135. Response to a vaccine antigen component was defined as:
- For initially seronegative subject, post-vaccination serum bactericidal assay using rabbit complement (rSBA) titer ≥ 1:32;
- For initially seropositive subject, at least 4-fold increase in rSBA titer from pre- to post-vaccination.

Comparison groups	Nimenrix™ 2-11 years of age Primary Phase Group v Mencevax™ 2-11 years of age Primary Phase Group

Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in percentage
Point estimate	4.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	12.21

Notes:

[3] - Criterion indicative of non-inferiority: lower limit of the standardized asymptotic 95% confidence interval (CI) for the group difference (MenACWY-TT minus MenACWY) in the percentage of subjects with bactericidal vaccine response is greater than or equal to -15% for each of the four antigens.

Statistical analysis title	Difference in VRR to rSBA-MenY

Statistical analysis description:

To evaluate the non-inferiority of MenACWY-TT conjugate vaccine compared to MenACWY plain polysaccharide vaccine in terms of the vaccine response to MenY. Response to a vaccine antigen component was defined as:
- For initially seronegative subject, post-vaccination serum bactericidal assay using rabbit complement (rSBA) titer ≥ 1:32;
- For initially seropositive subject, at least 4-fold increase in rSBA titer from pre- to post-vaccination.

Comparison groups	Nimenrix™ 2-11 years of age Primary Phase Group v Mencevax™ 2-11 years of age Primary Phase Group
Number of subjects included in analysis	289
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in percentage
Point estimate	16.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.99
upper limit	26.78

Notes:

[4] - Criterion indicative of non-inferiority: lower limit of the standardized asymptotic 95% confidence interval (CI) for the group difference (MenACWY-TT minus MenACWY) in the percentage of subjects with bactericidal vaccine response is greater than or equal to -15% for each of the four antigens.

Primary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8[5]

End point description:

End point type	Primary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	68		
Units: Subjects				
rSBA-MenA (PRE) [N= 191;65]	81	26		
rSBA-MenA (PI[M1]) [N= 222;63]	222	22		
rSBA-MenC (PRE) [N= 203;61]	80	19		
rSBA-MenC (PI[M1]) [N= 220;68]	220	67		
rSBA-MenW-135 (PRE) [N=208;62]	59	24		
rSBA-MenW-135 (PI[M1]) [N=222;63]	222	27		
rSBA-MenY (PRE) [N=208;67]	115	41		
rSBA-MenY (PI[M1]) [N=222;66]	222	49		

Statistical analyses

Statistical analysis title	Difference in VRR to rSBA-MenC

Statistical analysis description:

To evaluate the non-inferiority of the vaccine response induced by MenACWY-TT conjugate vaccine when compared to the licensed MenC-CRM vaccine for MenC as measured by rSBA.

Comparison groups	Meningitec™ 1-2 years of age Group v Nimenrix™ 1-2 years of age Group
Number of subjects included in analysis	290
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference in percentage
Point estimate	1.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	7.89

Notes:

[6] - Criterion indicative of non-inferiority (serogroup C only): one month after vaccination, the lower limit of the 2-sided standardized asymptotic 95% CI for the group difference (MenACWY-TT minus MenC-CRM) in the percentage of subjects with rSBA titer ≥ 1:8 is greater than or equal to the pre-defined clinical limit of -15%.

Primary: Percentage of subjects with rSBA antibodies titers ≥ 1:8

End point title	Percentage of subjects with rSBA antibodies titers ≥ 1:8[7][8]

End point description:

End point type	Primary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[7] - 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 results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group			
Subject group type	Reporting group			
Number of subjects analysed	222			
Units: Percentage				
number (confidence interval 95%)				
rSBA-MenA (PRE) [N=191]	42.4 (35.3 to 49.8)			
rSBA-MenA [PI(M1)] [N=222]	100 (98.4 to 100)			
rSBA-MenC (PRE) [N=203]	39.4 (32.6 to 46.5)			
rSBA-MenC [PI(M1)] [N=220]	100 (98.3 to 100)			
rSBA-MenW-135 (PRE) [N=208]	28.4 (22.3 to 35)			
rSBA-MenW-135 [PI(M1)] [N=222]	100 (98.4 to 100)			
rSBA-MenY (PRE) [N=208]	55.3 (48.3 to 62.2)			
rSBA-MenY [PI(M1)] [N=222]	100 (98.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8 and ≥ 1:128

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8 and ≥ 1:128
End point description:	
These analyses were performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe:	
Prior to (PRE) and one month after vaccination [PI(M1)]	

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	75		
Units: Subjects				
rSBA-MenA (PRE) ≥ 1:8 [N=185;62]	124	40		
rSBA-MenA (PRE) ≥ 1:128 [N=185;62]	96	32		

rSBA-MenA (PI[M1]) ≥ 1:8 [N=225;75]	225	75		
rSBA-MenA (PI[M1]) ≥ 1:128 [N=225;75]	224	75		
rSBA-MenC (PRE) ≥ 1:8 [N=212;70]	133	36		
rSBA-MenC (PRE) ≥ 1:128 [N=212;70]	59	19		
rSBA-MenC (PI[M1]) ≥ 1:8 [N=225;74]	225	74		
rSBA-MenC (PI[M1]) ≥ 1:128 [N=225;74]	224	70		
rSBA-MenW-135 (PRE) ≥ 1:8 [N=199;68]	120	39		
rSBA-MenW-135 (PRE) ≥ 1:128 [N=199;68]	90	24		
rSBA-MenW-135 (PI[M1]) ≥ 1:8 [N=225;75]	225	75		
rSBA-MenW-135 (PI[M1]) ≥ 1:128 [N=225;75]	225	75		
rSBA-MenY (PRE) ≥ 1:8 [N=219;70]	147	42		
rSBA-MenY (PRE) ≥ 1:128 [N=219;70]	98	28		
rSBA-MenY (PI[M1]) ≥ 1:8 [N=225;75]	225	75		
rSBA-MenY (PI[M1]) ≥ 1:128 [N=225;75]	224	73		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

These analyses were performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	75		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=185;62]	57.9 (43.3 to 77.5)	58.2 (33.8 to 100.1)		
rSBA-MenA (PI[M1]) [N=225;75]	7300.9 (6586 to 8093.4)	2033.4 (1667.1 to 2480.2)		
rSBA-MenC (PRE) [N=212;70]	33.5 (26 to 43.1)	24.1 (15.2 to 38.2)		

rSBA-MenC (PI[M1]) [N=225;74]	2435.3 (2105.8 to 2816.3)	750.2 (555.2 to 1013.7)		
rSBA-MenW-135 (PRE) [N=199;68]	43.1 (32.4 to 57.4)	40.1 (23.9 to 67.3)		
rSBA-MenW-135 (PI[M1]) [N=225;75]	11777 (10666.2 to 13003.5)	2186.3 (1723.1 to 2773.9)		
rSBA-MenY (PRE) [N=219;70]	57.3 (43.7 to 75.2)	45.5 (26.8 to 77)		
rSBA-MenY (PI[M1]) [N=225;75]	6641.4 (6044.3 to 7297.4)	1409.9 (1085.9 to 1830.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL and ≥ 2.0 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL and ≥ 2.0 µg/mL[9]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	168	51		
Units: Subjects				
Anti-PSA (PRE) ≥ 0.3 µg/mL [N=147;43]	10	4		
Anti-PSA (PRE) ≥ 2.0 µg/mL [N=147;43]	2	1		
Anti-PSA [PI(M1)] ≥ 0.3 µg/mL [N=162;36]	162	2		
Anti-PSA [PI(M1)] ≥ 2.0 µg/mL [N=162;36]	162	1		
Anti-PSC (PRE) ≥ 0.3 µg/mL [N=141;42]	3	1		
Anti-PSC (PRE) ≥ 2.0 µg/mL [N=141;42]	1	1		
Anti-PSC [PI(M1)] ≥ 0.3 µg/mL [N=168;51]	168	51		
Anti-PSC [PI(M1)] ≥ 2.0 µg/mL [N=168;51]	166	50		

Anti-PSW-135 (PRE) ≥ 0.3 µg/mL [N=141;39]	2	0		
Anti-PSW-135 (PRE) ≥ 2.0 µg/mL [N=141;39]	1	0		
Anti-PSW-135 [PI(M1)] ≥ 0.3 µg/mL [N=143;36]	143	0		
Anti-PSW-135 [PI(M1)] ≥ 2.0 µg/mL [N=143;36]	131	0		
Anti-PSY (PRE) ≥ 0.3 µg/mL [N=107;30]	1	1		
Anti-PSY (PRE) ≥ 2.0 µg/mL [N=107;30]	0	0		
Anti-PSY [PI(M1)] ≥ 0.3 µg/mL [N=152;32]	152	0		
Anti-PSY [PI(M1)] ≥ 2.0 µg/mL [N=152;32]	147	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations[10]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	168	51		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PRE) [N=147;43]	0.17 (0.15 to 0.18)	0.18 (0.14 to 0.23)		
Anti-PSA [PI(M1)] [N=162;36]	33.36 (29.07 to 38.27)	0.17 (0.14 to 0.2)		
Anti-PSC (PRE) [N=141;42]	0.16 (0.15 to 0.17)	0.16 (0.14 to 0.18)		
Anti-PSC [PI(M1)] [N=168;51]	13.47 (12 to 15.12)	8.29 (6.8 to 10.1)		
Anti-PSW-135 (PRE) [N=141;39]	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.15)		
Anti-PSW-135 [PI(M1)] [N=143;36]	6.86 (5.87 to 8.02)	0.15 (0.15 to 0.15)		

Anti-PSY (PRE) [N=107;30]	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.17)		
Anti-PSY [PI(M1)] [N=152;32]	10.35 (9.12 to 11.74)	0.15 (0.15 to 0.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-TT antibody concentrations ≥ 0.1 IU/mL

End point title	Number of subjects with anti-TT antibody concentrations ≥ 0.1 IU/mL[11]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	6		
Units: Subjects				
Anti-TT (PRE) [N=19;6]	18	5		
Anti-TT [PI(M1)] [N=30;4]	30	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-TT antibody concentrations

End point title	Anti-TT antibody concentrations[12]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the

results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	6		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-TT (PRE) [N=19;6]	1.226 (0.609 to 2.47)	0.57 (0.102 to 3.188)		
Anti-TT [PI(M1)] [N=30;4]	14.199 (9.628 to 20.94)	1.341 (0.316 to 5.686)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8
End point description:	
End point type	Secondary
End point timeframe: Persistence Year 1	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	66		
Units: Subjects				
rSBA-MenA (PRE) [N=185;64]	80	26		
rSBA-MenA (PI[M1]) [N=216;61]	216	21		
rSBA-MenA (PI[M12]) [N=212;49]	210	16		
rSBA-MenC (PRE) [N=197;61]	78	20		
rSBA-MenC (PI[M1]) [N=214;66]	214	66		
rSBA-MenC (PI[M12]) [N=207;63]	203	50		
rSBA-MenW-135 (PRE) [N=202;62]	57	23		
rSBA-MenW-135 (PI[M1]) [N=216;61]	216	26		
rSBA-MenW-135 (PI[M12]) [N=216;64]	216	38		
rSBA-MenY (PRE) [N=202;66]	113	40		
rSBA-MenY (PI[M1]) [N=216;65]	216	48		
rSBA-MenY (PI[M12]) [N=216;66]	214	42		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	66		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=185;64]	22.6 (16.7 to 30.6)	20.7 (12.3 to 34.9)		
rSBA-MenA (PI[M1]) [N=216;61]	3684.2 (3302.8 to 4109.5)	16.9 (9.9 to 29)		
rSBA-MenA (PI[M12]) [N=212;49]	967 (843 to 1109.3)	18.3 (9.5 to 35.1)		
rSBA-MenC (PRE) [N=197;61]	14 (11 to 17.6)	10.2 (7.1 to 14.7)		
rSBA-MenC (PI[M1]) [N=214;66]	864.2 (763.6 to 978.2)	448.2 (327.5 to 613.6)		
rSBA-MenC (PI[M12]) [N=207;63]	195.3 (166.3 to 229.3)	77.1 (49.1 to 121.1)		
rSBA-MenW-135 (PRE) [N=202;62]	11.3 (8.9 to 14.4)	15.5 (9.6 to 24.9)		
rSBA-MenW-135 (PI[M1]) [N=216;61]	5386.9 (4859.3 to 5971.7)	20.2 (12.3 to 33.2)		
rSBA-MenW-135 (PI[M12]) [N=216;64]	855.1 (757.1 to 965.9)	36.7 (22.6 to 59.7)		
rSBA-MenY (PRE) [N=202;66]	34.6 (26.1 to 45.9)	44.1 (26.2 to 74.3)		
rSBA-MenY (PI[M1]) [N=216;65]	2836.5 (2536.4 to 3172)	78.1 (46.6 to 130.9)		
rSBA-MenY (PI[M12]) [N=216;66]	766.4 (661 to 888.5)	65.1 (36.9 to 114.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	75		
Units: Subjects				
rSBA-MenA (PRE) [N=175;62]	118	40		
rSBA-MenA (PI[M1]) [N=214;75]	214	75		
rSBA-MenA (PI[M12]) [N=216;71]	215	64		
rSBA-MenC (PRE) [N=202;70]	128	36		
rSBA-MenC (PI[M1]) [N=214;74]	214	74		
rSBA-MenC (PI[M12]) [N=215;65]	214	52		
rSBA-MenW-135 (PRE) [N=190;68]	113	39		
rSBA-MenW-135 (PI[M1]) [N=214;75]	214	75		
rSBA-MenW-135 (PI[M12]) [N=216;75]	216	75		
rSBA-MenY (PRE) [N=210;70]	141	42		
rSBA-MenY (PI[M1]) [N=214;75]	214	75		
rSBA-MenY (PI[M12]) [N=216;71]	216	64		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

This analysis was performed at the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	75		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=175;62]	59.6 (44.1 to 80.3)	58.2 (33.8 to 100.1)		
rSBA-MenA (PI[M1]) [N=214;75]	7395.3 (6652.7 to 8220.7)	2033.4 (1667.1 to 2480.2)		
rSBA-MenA (PI[M12]) [N=216;71]	2448.1 (2149.6 to 2788.1)	358.5 (230.2 to 558.4)		
rSBA-MenC (PRE) [N=202;70]	34.4 (26.6 to 44.5)	24.1 (15.2 to 38.2)		
rSBA-MenC (PI[M1]) [N=214;74]	2488.5 (2145 to 2887)	750.2 (555.2 to 1013.7)		
rSBA-MenC (PI[M12]) [N=215;65]	489.5 (419.5 to 571.1)	113.5 (67.3 to 191.5)		
rSBA-MenW-135 (PRE) [N=190;68]	41.6 (31.1 to 55.8)	40.1 (23.9 to 67.3)		
rSBA-MenW-135 (PI[M1]) [N=214;75]	11943.7 (10782.7 to 13229.7)	2186.3 (1723.1 to 2773.9)		
rSBA-MenW-135 (PI[M12]) [N=216;75]	2983.3 (2628.2 to 3386.3)	463 (367.4 to 583.5)		
rSBA-MenY (PRE) [N=210;70]	57.4 (43.5 to 75.9)	45.5 (26.8 to 77)		
rSBA-MenY (PI[M1]) [N=214;75]	6666.3 (6057.7 to 7336.1)	1409.9 (1085.9 to 1830.5)		
rSBA-MenY (PI[M12]) [N=216;71]	2172.1 (1939.6 to 2432.5)	332.4 (213.5 to 517.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point description:

End point type	Secondary

End point timeframe:
Persistence Year 1

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	49		
Units: Subjects				
Anti-PSA (PRE) [N=142;44]	9	4		
Anti-PSA (PI[M1]) [N=155;35]	155	2		
Anti-PSA (PI[M12]) [N=131;38]	118	3		
Anti-PSC (PRE) [N=137;41]	3	1		
Anti-PSC (PI[M1]) [N=161;49]	161	49		
Anti-PSC (PI[M12]) [N=128;35]	73	17		
Anti-PSW-135 (PRE) [N=137;38]	2	0		
Anti-PSW-135 (PI[M1]) [N=138;35]	138	0		
Anti-PSW-135 (PI[M12]) [N=132;32]	124	0		
Anti-PSY (PRE) [N=104;30]	1	1		
Anti-PSY (PI[M1]) [N=145;31]	145	0		
Anti-PSY (PI[M12]) [N=157;45]	153	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations

End point description:

End point type	Secondary

End point timeframe:
Persistence Year 1

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	49		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PRE) [N=142;44]	0.17 (0.15 to 0.18)	0.18 (0.14 to 0.23)		
Anti-PSA (PI[M1]) [N=155;35]	33.31 (28.94 to 38.35)	0.17 (0.14 to 0.2)		

Anti-PSA (PI[M12]) [N=131;38]	1.07 (0.89 to 1.3)	0.17 (0.15 to 0.18)		
Anti-PSC (PRE) [N=137;41]	0.16 (0.15 to 0.17)	0.16 (0.14 to 0.19)		
Anti-PSC (PI[M1]) [N=161;49]	13.44 (11.93 to 15.14)	8.53 (6.97 to 10.43)		
Anti-PSC (PI[M12]) [N=128;35]	0.39 (0.33 to 0.46)	0.34 (0.24 to 0.47)		
Anti-PSW-135 (PRE) [N=137;38]	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.15)		
Anti-PSW-135 (PI[M1]) [N=138;35]	6.87 (5.85 to 8.07)	0.15 (0.15 to 0.15)		
Anti-PSW-135 (PI[M12]) [N=132;32]	1.33 (1.13 to 1.56)	0.15 (0.15 to 0.15)		
Anti-PSY (PRE) [N=104;30]	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.17)		
Anti-PSY (PI[M1]) [N=145;31]	10.21 (8.96 to 11.62)	0.15 (0.15 to 0.15)		
Anti-PSY (PI[M12]) [N=157;45]	1.97 (1.7 to 2.28)	0.16 (0.15 to 0.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	75		
Units: Subjects				
Anti-PSA (PRE) [N=209;75]	26	12		
Anti-PSA (PI[M1]) [N=213;74]	213	73		
Anti-PSA (PI[M12]) [N=213;73]	209	70		
Anti-PSC (PRE) [N=216;74]	29	6		
Anti-PSC (PI[M1]) [N=213;74]	213	74		
Anti-PSC (PI[M12]) [N=216;75]	169	74		
Anti-PSW-135 (PRE) [N=216;75]	2	1		
Anti-PSW-135 (PI[M1]) [N=213;74]	213	72		
Anti-PSW-135 (PI[M12]) [N=210;72]	206	65		
Anti-PSY (PRE) [N=215;74]	4	0		
Anti-PSY (PI[M1]) [N=214;74]	214	72		

Anti-PSY (PI[M12]) [N=215;74]	213	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	216	75		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PRE) [N=209;75]	0.19 (0.17 to 0.21)	0.2 (0.16 to 0.23)		
Anti-PSA (PI[M1]) [N=213;74]	35.95 (31.79 to 40.65)	10.34 (7.79 to 13.72)		
Anti-PSA (PI[M12]) [N=213;73]	2.33 (1.94 to 2.79)	4.05 (2.88 to 5.68)		
Anti-PSC (PRE) [N=216;74]	0.2 (0.18 to 0.23)	0.19 (0.15 to 0.22)		
Anti-PSC (PI[M1]) [N=213;74]	13.34 (11.7 to 15.2)	14.53 (11.13 to 18.95)		
Anti-PSC (PI[M12]) [N=216;75]	0.76 (0.64 to 0.91)	4.4 (3.2 to 6.04)		
Anti-PSW-135 (PRE) [N=216;75]	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.16)		
Anti-PSW-135 (PI[M1]) [N=213;74]	6.26 (5.43 to 7.22)	4.62 (3.37 to 6.35)		
Anti-PSW-135 (PI[M12]) [N=210;72]	1.94 (1.7 to 2.22)	2.21 (1.54 to 3.15)		
Anti-PSY (PRE) [N=215;74]	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.15)		
Anti-PSY (PI[M1]) [N=214;74]	11.2 (9.86 to 12.71)	15.45 (11.42 to 20.91)		
Anti-PSY (PI[M12]) [N=215;74]	2.76 (2.43 to 3.15)	5.77 (4.2 to 7.93)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	199	52		
Units: Subjects				
rSBA-MenA (PRE) [N=171;48]	73	21		
rSBA-MenA (PI[M1]) [N=199;47]	199	18		
rSBA-MenA (PI[M12]) [N=195;36]	193	13		
rSBA-MenA (PI[M24]) [N=190;45]	188	30		
rSBA-MenC (PRE) [N=181;47]	72	16		
rSBA-MenC (PI[M1]) [N=197;50]	197	50		
rSBA-MenC (PI[M12]) [N=189;47]	188	47		
rSBA-MenC (PI[M24]) [N=197;52]	185	38		
rSBA-MenW-135 (PRE) [N=188;47]	54	16		
rSBA-MenW-135 (PI[M1]) [N=199;48]	199	19		
rSBA-MenW-135 (PI[M12]) [N=198;49]	198	29		
rSBA-MenW-135 (PI[M24]) [N=199;44]	198	24		
rSBA-MenY (PRE) [N=185;50]	104	31		
rSBA-MenY (PI[M1]) [N=199;50]	199	38		
rSBA-MenY (PI[M12]) [N=198;50]	196	35		
rSBA-MenY (PI[M24]) [N=197;50]	193	37		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	199	52		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=171;48]	22.7 (16.5 to 31.2)	24 (12.9 to 44.6)		
rSBA-MenA (PI[M1]) [N=199;47]	3743 (3341.1 to 4193.2)	20 (10.6 to 37.8)		
rSBA-MenA (PI[M12]) [N=195;36]	961.4 (830 to 1113.5)	21.5 (9.8 to 47)		
rSBA-MenA (PI[M24]) [N=190;45]	567.7 (489.8 to 658)	51.3 (29 to 90.8)		
rSBA-MenC (PRE) [N=181;47]	13.7 (10.8 to 17.5)	11.2 (7.2 to 17.4)		
rSBA-MenC (PI[M1]) [N=197;50]	870.9 (766 to 990.1)	626.4 (442.7 to 886.3)		
rSBA-MenC (PI[M12]) [N=189;47]	203.9 (174.2 to 238.6)	163.7 (118.6 to 226)		
rSBA-MenC (PI[M24]) [N=197;52]	117.4 (97.1 to 141.9)	57.7 (33.5 to 99.3)		
rSBA-MenW-135 (PRE) [N=188;47]	11.5 (8.9 to 14.7)	13 (7.8 to 21.8)		
rSBA-MenW-135 (PI[M1]) [N=199;48]	5424.4 (4867.9 to 6044.4)	17.6 (10.2 to 30.5)		
rSBA-MenW-135 (PI[M12]) [N=198;49]	856.6 (755.4 to 971.3)	35.4 (20.4 to 61.5)		
rSBA-MenW-135 (PI[M24]) [N=199;44]	415.9 (362.4 to 477.3)	27.5 (15.7 to 48.1)		
rSBA-MenY (PRE) [N=185;50]	34 (25.4 to 45.5)	44.6 (24.8 to 80.2)		
rSBA-MenY (PI[M1]) [N=199;50]	2797.6 (2494.9 to 3137.1)	86 (49.3 to 150)		
rSBA-MenY (PI[M12]) [N=198;50]	749.4 (642.9 to 873.6)	82.7 (44.7 to 152.9)		
rSBA-MenY (PI[M24]) [N=197;50]	504.1 (421 to 603.6)	93.5 (51.8 to 168.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

End point type	Secondary

End point timeframe:
Persistence Year 2

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	59		
Units: Subjects				
rSBA-MenA (PRE) [N=170;48]	113	32		
rSBA-MenA (PI[M1]) [N=209;59]	209	59		
rSBA-MenA (PI[M12]) [N=208;57]	207	53		
rSBA-MenA (PI[M24]) [N=208;56]	208	51		
rSBA-MenC (PRE) [N=196;56]	125	34		
rSBA-MenC (PI[M1]) [N=209;59]	209	59		
rSBA-MenC (PI[M12]) [N=207;49]	207	49		
rSBA-MenC (PI[M24]) [N=210;59]	207	39		
rSBA-MenW-135 (PRE) [N=189;53]	115	32		
rSBA-MenW-135 (PI[M1]) [N=209;59]	209	59		
rSBA-MenW-135 (PI[M12]) [N=208;59]	208	59		
rSBA-MenW-135 (PI[M24]) [N=210;54]	209	46		
rSBA-MenY (PRE) [N=204;54]	138	31		
rSBA-MenY (PI[M1]) [N=209;59]	209	59		
rSBA-MenY (PI[M12]) [N=208;55]	208	52		
rSBA-MenY (PI[M24]) [N=210;55]	210	41		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:
This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:
Persistence Year 2

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	59		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=170;48]	57.1 (42.1 to 77.4)	64.5 (34.9 to 119)		
rSBA-MenA (PI[M1]) [N=209;59]	7392.2 (6645 to 8223.3)	2230.8 (1797.6 to 2768.3)		
rSBA-MenA (PI[M12]) [N=208;57]	2475.3 (2170.5 to 2822.9)	450.6 (289 to 702.7)		
rSBA-MenA (PI[M24]) [N=208;56]	1333.4 (1181.9 to 1504.2)	202.5 (135.3 to 303)		
rSBA-MenC (PRE) [N=196;56]	35.4 (27.2 to 46)	33.7 (20 to 56.8)		
rSBA-MenC (PI[M1]) [N=209;59]	2475.6 (2128.8 to 2878.9)	966.7 (695.7 to 1343.2)		
rSBA-MenC (PI[M12]) [N=207;49]	490.3 (421.7 to 570.2)	277 (187.4 to 409.6)		
rSBA-MenC (PI[M24]) [N=210;59]	256 (213.9 to 306.2)	59.9 (33 to 108.7)		
rSBA-MenW-135 (PRE) [N=189;53]	43.9 (32.8 to 58.8)	46.2 (25.7 to 83)		
rSBA-MenW-135 (PI[M1]) [N=209;59]	11892.6 (10744.2 to 13163.7)	2215 (1679.2 to 2921.7)		
rSBA-MenW-135 (PI[M12]) [N=208;59]	2969.7 (2612.5 to 3375.9)	496.2 (383.5 to 641.9)		
rSBA-MenW-135 (PI[M24]) [N=210;54]	1298 (1135.5 to 1483.7)	144 (90.1 to 230.2)		
rSBA-MenY (PRE) [N=204;54]	58.3 (44 to 77.3)	40.9 (22.3 to 75)		
rSBA-MenY (PI[M1]) [N=209;59]	6594.5 (5971.2 to 7282.9)	1574.2 (1177.1 to 2105.3)		
rSBA-MenY (PI[M12]) [N=208;55]	2115.5 (1886.4 to 2372.5)	418 (269.2 to 649.2)		
rSBA-MenY (PI[M24]) [N=210;55]	1530.2 (1339.2 to 1748.4)	96.9 (54.1 to 173.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	161	39		
Units: Subjects				
Anti-PSA (PRE) [N=132;35]	7	4		
Anti-PSA (PI[M1]) [N=143;27]	143	2		
Anti-PSA (PI[M12]) [N=121;31]	109	2		
Anti-PSA (PI[M24]) [N=140;39]	107	7		
Anti-PSC (PRE) [N=126;31]	3	1		
Anti-PSC (PI[M1]) [N=148;35]	148	35		
Anti-PSC (PI[M12]) [N=117;30]	68	15		
Anti-PSC (PI[M24]) [N=107;22]	38	6		
Anti-PSW-135 (PRE) [N=127;29]	1	0		
Anti-PSW-135 (PI[M1]) [N=129;24]	129	0		
Anti-PSW-135 (PI[M12]) [N=122;26]	114	0		
Anti-PSW-135 (PI[M24]) [N=135;32]	98	0		
Anti-PSY (PRE) [N=96;22]	1	1		
Anti-PSY (PI[M1]) [N=135;24]	135	0		
Anti-PSY (PI[M12]) [N=144;35]	140	1		
Anti-PSY (PI[M24]) [N=161;33]	144	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	148	39		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PRE) [N=132;35]	0.16 (0.15 to 0.18)	0.19 (0.14 to 0.25)		
Anti-PSA (PI[M1]) [N=143;27]	32.63 (28.2 to 37.75)	0.18 (0.14 to 0.22)		
Anti-PSA (PI[M12]) [N=121;31]	1.08 (0.89 to 1.32)	0.16 (0.14 to 0.18)		
Anti-PSA (PI[M24]) [N=140;39]	0.59 (0.5 to 0.69)	0.19 (0.16 to 0.23)		
Anti-PSC (PRE) [N=126;31]	0.16 (0.15 to 0.17)	0.16 (0.14 to 0.2)		
Anti-PSC (PI[M1]) [N=148;35]	13.58 (12.01 to 15.36)	9.16 (7.31 to 11.47)		
Anti-PSC (PI[M12]) [N=117;30]	0.39 (0.33 to 0.47)	0.36 (0.24 to 0.53)		
Anti-PSC (PI[M24]) [N=107;22]	0.26 (0.22 to 0.3)	0.24 (0.17 to 0.36)		
Anti-PSW-135 (PRE) [N=127;29]	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.15)		
Anti-PSW-135 (PI[M1]) [N=129;24]	6.58 (5.6 to 7.74)	0.15 (0.15 to 0.15)		
Anti-PSW-135 (PI[M12]) [N=122;26]	1.33 (1.12 to 1.58)	0.15 (0.15 to 0.15)		
Anti-PSW-135 (PI[M24]) [N=135;32]	0.65 (0.54 to 0.79)	0.15 (0.15 to 0.15)		
Anti-PSY (PRE) [N=96;22]	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.18)		
Anti-PSY (PI[M1]) [N=135;24]	10.22 (8.96 to 11.67)	0.15 (0.15 to 0.15)		
Anti-PSY (PI[M12]) [N=144;35]	1.95 (1.67 to 2.27)	0.15 (0.15 to 0.17)		
Anti-PSY (PI[M24]) [N=161;33]	1.12 (0.96 to 1.3)	0.16 (0.14 to 0.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	59		
Units: Subjects				
Anti-PSA (PRE) [N=203;59]	24	11		
Anti-PSA (PI[M1]) [N=208;59]	208	58		
Anti-PSA (PI[M12]) [N=205;57]	201	54		
Anti-PSA (PI[M24]) [N=199;56]	187	54		
Anti-PSC (PRE) [N=210;58]	29	6		
Anti-PSC (PI[M1]) [N=208;59]	208	59		
Anti-PSC (PI[M12]) [N=208;59]	163	58		
Anti-PSC (PI[M24]) [N=208;59]	131	57		
Anti-PSW-135 (PRE) [N=210;59]	3	1		
Anti-PSW-135 (PI[M1]) [N=208;59]	208	57		
Anti-PSW-135 (PI[M12]) [N=202;57]	198	52		
Anti-PSW-135 (PI[M24]) [N=204;58]	181	52		
Anti-PSY (PRE) [N=209;58]	5	0		
Anti-PSY (PI[M1]) [N=209;58]	209	56		
Anti-PSY (PI[M12]) [N=207;59]	205	56		
Anti-PSY (PI[M24]) [N=205;54]	198	50		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	210	59		
Units: µg/mL				
geometric mean (confidence interval 95%)				

Anti-PSA (PRE) [N=203;59]	0.18 (0.17 to 0.2)	0.21 (0.17 to 0.26)		
Anti-PSA (PI[M1]) [N=208;59]	34.76 (30.83 to 39.19)	11.2 (8.1 to 15.47)		
Anti-PSA (PI[M12]) [N=205;57]	2.27 (1.9 to 2.71)	4.62 (3.13 to 6.82)		
Anti-PSA (PI[M24]) [N=199;56]	1.52 (1.28 to 1.81)	2.93 (2.07 to 4.14)		
Anti-PSC (PRE) [N=210;58]	0.2 (0.18 to 0.23)	0.2 (0.16 to 0.25)		
Anti-PSC (PI[M1]) [N=208;59]	12.94 (11.37 to 14.72)	15.28 (11.24 to 20.77)		
Anti-PSC (PI[M12]) [N=208;59]	0.75 (0.63 to 0.9)	4.98 (3.51 to 7.06)		
Anti-PSC (PI[M24]) [N=208;59]	0.54 (0.45 to 0.64)	2.81 (2.02 to 3.91)		
Anti-PSW-135 (PRE) [N=210;59]	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.16)		
Anti-PSW-135 (PI[M1]) [N=208;59]	6.16 (5.34 to 7.11)	4.5 (3.13 to 6.47)		
Anti-PSW-135 (PI[M12]) [N=202;57]	1.9 (1.66 to 2.17)	2.28 (1.53 to 3.4)		
Anti-PSW-135 (PI[M24]) [N=204;58]	1.15 (0.99 to 1.34)	1.32 (0.92 to 1.9)		
Anti-PSY (PRE) [N=209;58]	0.16 (0.15 to 0.16)	0.15 (0.15 to 0.15)		
Anti-PSY (PI[M1]) [N=209;58]	11.1 (9.76 to 12.63)	14.91 (10.45 to 21.28)		
Anti-PSY (PI[M12]) [N=207;59]	2.73 (2.39 to 3.11)	5.8 (4.01 to 8.39)		
Anti-PSY (PI[M24]) [N=205;54]	1.72 (1.49 to 1.98)	2.9 (1.98 to 4.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8
End point description: This analysis was performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe: Persistence Year 3	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	37		
Units: Subjects				
rSBA-MenA (PRE) [N=151;35]	65	15		

rSBA-MenA (PI[M1]) [N=177;32]	177	10		
rSBA-MenA (PI[M12]) [N=174;22]	172	7		
rSBA-MenA (PI[M24]) [N=165;30]	164	21		
rSBA-MenA (PI[M36]) [N=170;32]	168	27		
rSBA-MenC (PRE) [N=163;34]	71	12		
rSBA-MenC (PI[M1]) [N=175;36]	175	36		
rSBA-MenC (PI[M12]) [N=169;35]	169	35		
rSBA-MenC (PI[M24]) [N=171;36]	171	36		
rSBA-MenC (PI[M36]) [N=174;37]	158	36		
rSBA-MenW-135 (PRE) [N=167;33]	50	11		
rSBA-MenW-135 (PI[M1]) [N=177;36]	177	14		
rSBA-MenW-135 (PI[M12]) [N=176;35]	176	22		
rSBA-MenW-135 (PI[M24]) [N=173;30]	172	15		
rSBA-MenW-135 (PI[M36]) [N=174;33]	172	24		
rSBA-MenY (PRE) [N=166;36]	96	24		
rSBA-MenY (PI[M1]) [N=177;36]	177	29		
rSBA-MenY (PI[M12]) [N=176;35]	175	24		
rSBA-MenY (PI[M24]) [N=171;35]	168	27		
rSBA-MenY (PI[M36]) [N=177;36]	174	33		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers
End point description: This analysis was performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe: Persistence Year 3	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	37		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=151;35]	23 (16.4 to 32.2)	21.8 (10.8 to 44.1)		
rSBA-MenA (PI[M1]) [N=177;32]	3787.4 (3353.2 to 4277.8)	14.4 (7 to 29.4)		
rSBA-MenA (PI[M12]) [N=174;22]	974.4 (831 to 1142.4)	17.6 (6.5 to 47.6)		
rSBA-MenA (PI[M24]) [N=165;30]	575.2 (494 to 669.9)	56.5 (28.5 to 112.2)		

rSBA-MenA (PI[M36]) [N=170;32]	518.6 (447.6 to 600.8)	117.1 (65 to 211.2)		
rSBA-MenC (PRE) [N=163;34]	15.5 (11.9 to 20)	12 (6.9 to 20.9)		
rSBA-MenC (PI[M1]) [N=175;36]	887 (770.4 to 1021.2)	727.6 (478.7 to 1105.8)		
rSBA-MenC (PI[M12]) [N=169;35]	223.5 (192.2 to 259.8)	218.3 (157.9 to 301.8)		
rSBA-MenC (PI[M24]) [N=171;36]	141.2 (120.3 to 165.6)	158.6 (103.8 to 242.2)		
rSBA-MenC (PI[M36]) [N=174;37]	125.1 (96.7 to 162)	185.7 (118.3 to 291.5)		
rSBA-MenW-135 (PRE) [N=167;33]	11.7 (9 to 15.1)	12.6 (6.8 to 23.5)		
rSBA-MenW-135 (PI[M1]) [N=177;36]	5563.5 (4976.9 to 6219.4)	17.5 (9.2 to 33.6)		
rSBA-MenW-135 (PI[M12]) [N=176;35]	904.9 (792.5 to 1033.2)	37.9 (20.1 to 71.3)		
rSBA-MenW-135 (PI[M24]) [N=173;30]	439.3 (379 to 509.4)	22.9 (11.6 to 45.1)		
rSBA-MenW-135 (PI[M36]) [N=174;33]	439.8 (370.5 to 522)	64.5 (33.5 to 124.3)		
rSBA-MenY (PRE) [N=166;36]	37.4 (27.4 to 51)	52.5 (26.7 to 103.3)		
rSBA-MenY (PI[M1]) [N=177;36]	2875.6 (2540 to 3255.6)	101.5 (54.3 to 189.7)		
rSBA-MenY (PI[M12]) [N=176;35]	799.2 (683.3 to 934.7)	75.7 (36.2 to 158.3)		
rSBA-MenY (PI[M24]) [N=171;35]	532.8 (439.7 to 645.6)	100.6 (50.6 to 200)		
rSBA-MenY (PI[M36]) [N=177;36]	583.2 (479 to 709.9)	176 (97.6 to 317.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Persistence Year 3

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	37		
Units: Subjects				
rSBA-MenA (PRE) [N=162;31]	109	20		
rSBA-MenA (PI[M1]) [N=196;37]	196	37		
rSBA-MenA (PI[M12]) [N=196;36]	195	34		
rSBA-MenA (PI[M24]) [N=193;35]	193	33		
rSBA-MenA (PI[M36]) [N=192;34]	192	31		
rSBA-MenC (PRE) [N=184;35]	118	26		
rSBA-MenC (PI[M1]) [N=196;37]	196	37		
rSBA-MenC (PI[M12]) [N=195;34]	195	34		
rSBA-MenC (PI[M24]) [N=195;37]	195	37		
rSBA-MenC (PI[M36]) [N=192;37]	189	31		
rSBA-MenW-135 (PRE) [N=173;33]	107	22		
rSBA-MenW-135 (PI[M1]) [N=196;37]	196	37		
rSBA-MenW-135 (PI[M12]) [N=196;37]	196	37		
rSBA-MenW-135 (PI[M24]) [N=195;34]	194	30		
rSBA-MenW-135 (PI[M36]) [N=196;35]	196	29		
rSBA-MenY (PRE) [N=192;34]	127	19		
rSBA-MenY (PI[M1]) [N=196;37]	196	37		
rSBA-MenY (PI[M12]) [N=196;34]	196	32		
rSBA-MenY (PI[M24]) [N=195;37]	195	30		
rSBA-MenY (PI[M36]) [N=195;37]	195	30		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers
End point description: This analysis was performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe: Persistence Year 3	

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	196	37		
Units: Titers				
geometric mean (confidence interval 95%)				

rSBA-MenA (PRE) [N=162;31]	58.4 (42.8 to 79.6)	69.8 (30.6 to 158.8)		
rSBA-MenA (PI[M1]) [N=196;37]	7513.7 (6740.4 to 8375.7)	2244.3 (1737.7 to 2898.6)		
rSBA-MenA (PI[M12]) [N=196;36]	2533.4 (2211.6 to 2902.1)	576.2 (334.8 to 991.7)		
rSBA-MenA (PI[M24]) [N=193;35]	1352.7 (1191.4 to 1535.7)	240.1 (149.5 to 385.7)		
rSBA-MenA (PI[M36]) [N=192;34]	1184.2 (1054.2 to 1330.3)	218.8 (128.9 to 371.5)		
rSBA-MenC (PRE) [N=184;35]	36.5 (27.8 to 48)	61.3 (31.4 to 119.7)		
rSBA-MenC (PI[M1]) [N=196;37]	2524.9 (2162.1 to 2948.5)	1433.7 (939.4 to 2188)		
rSBA-MenC (PI[M12]) [N=195;34]	509.4 (439.4 to 590.6)	437.6 (282.9 to 676.8)		
rSBA-MenC (PI[M24]) [N=195;37]	273.1 (229.3 to 325.1)	237.9 (144 to 393)		
rSBA-MenC (PI[M36]) [N=192;37]	244.3 (200.8 to 297.3)	163.5 (83.8 to 319.2)		
rSBA-MenW-135 (PRE) [N=173;33]	45.4 (33.5 to 61.5)	57.4 (27.6 to 119.4)		
rSBA-MenW-135 (PI[M1]) [N=196;37]	12158.8 (10949.9 to 13501.1)	2602.6 (1795.6 to 3772.4)		
rSBA-MenW-135 (PI[M12]) [N=196;37]	3064.7 (2692.8 to 3488)	587 (411.3 to 837.9)		
rSBA-MenW-135 (PI[M24]) [N=195;34]	1324.4 (1154.4 to 1519.4)	182.8 (104 to 321.2)		
rSBA-MenW-135 (PI[M36]) [N=196;35]	1737.1 (1503.8 to 2006.7)	112.9 (59.9 to 212.6)		
rSBA-MenY (PRE) [N=192;34]	55.4 (41.3 to 74.3)	37.2 (17.3 to 80.4)		
rSBA-MenY (PI[M1]) [N=196;37]	6655.7 (6009.1 to 7372)	1813.8 (1235.6 to 2662.5)		
rSBA-MenY (PI[M12]) [N=196;34]	2164 (1924.2 to 2433.6)	467.5 (261.3 to 836.5)		
rSBA-MenY (PI[M24]) [N=195;37]	1556.4 (1355.9 to 1786.6)	116.2 (59.3 to 227.7)		
rSBA-MenY (PI[M36]) [N=195;37]	1551.6 (1381.2 to 1743.1)	103.8 (54.3 to 198.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	31		
Units: Subjects				
rSBA-MenA (PRE) [N=130;30]	62	11		
rSBA-MenA (PI[M1]) [N=152;26]	152	7		
rSBA-MenA (PI[M12]) [N=150;19]	148	6		
rSBA-MenA (PI[M24]) [N=143;28]	142	19		
rSBA-MenA (PI[M36]) [N=144;26]	143	22		
rSBA-MenA (PI[M48]) [N=136;24]	133	21		
rSBA-MenC (PRE) [N=138;30]	57	13		
rSBA-MenC (PI[M1]) [N=150;29]	150	29		
rSBA-MenC (PI[M12]) [N=146;29]	146	29		
rSBA-MenC (PI[M24]) [N=148;31]	148	31		
rSBA-MenC (PI[M36]) [N=148;30]	147	30		
rSBA-MenC (PI[M48]) [N=137;30]	125	27		
rSBA-MenW-135 (PRE) [N=143;28]	44	8		
rSBA-MenW-135 (PI[M1]) [N=152;29]	152	12		
rSBA-MenW-135 (PI[M12]) [N=152;29]	152	17		
rSBA-MenW-135 (PI[M24]) [N=149;25]	148	12		
rSBA-MenW-135 (PI[M36]) [N=147;28]	146	20		
rSBA-MenW-135 (PI[M48]) [N=138;27]	133	18		
rSBA-MenY (PRE) [N=143;31]	83	21		
rSBA-MenY (PI[M1]) [N=152;29]	152	25		
rSBA-MenY (PI[M12]) [N=152;30]	151	22		
rSBA-MenY (PI[M24]) [N=147;30]	146	23		
rSBA-MenY (PI[M36]) [N=150;29]	148	27		
rSBA-MenY (PI[M48]) [N=138;29]	134	23		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	31		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=130;30]	27.9 (19.2 to 40.4)	18.1 (8.3 to 39.3)		
rSBA-MenA (PI[M1]) [N=152;26]	3911.7 (3443.2 to 4444)	12.4 (5.6 to 27.4)		
rSBA-MenA (PI[M12]) [N=150;19]	938.4 (790.3 to 1114.3)	15.9 (5.6 to 45)		
rSBA-MenA (PI[M24]) [N=143;28]	533 (451.6 to 629)	53.8 (25.9 to 112)		
rSBA-MenA (PI[M36]) [N=144;26]	503 (432.3 to 585.3)	129.3 (65.9 to 254)		
rSBA-MenA (PI[M48]) [N=136;24]	623.9 (507.1 to 767.6)	157.4 (79.1 to 313)		
rSBA-MenC (PRE) [N=138;30]	14.9 (11.2 to 19.9)	15.4 (8.3 to 28.5)		
rSBA-MenC (PI[M1]) [N=150;29]	922.5 (794.7 to 1070.8)	846.2 (537.3 to 1332.8)		
rSBA-MenC (PI[M12]) [N=146;29]	236.8 (199.7 to 280.7)	233.9 (160.3 to 341.5)		
rSBA-MenC (PI[M24]) [N=148;31]	162.5 (138.2 to 191.1)	185.3 (116.9 to 293.6)		
rSBA-MenC (PI[M36]) [N=148;30]	176.1 (138.6 to 223.9)	210.3 (139.6 to 316.8)		
rSBA-MenC (PI[M48]) [N=137;30]	141.9 (103.8 to 194)	150.5 (73.4 to 308.6)		
rSBA-MenW-135 (PRE) [N=143;28]	11.9 (9 to 15.7)	10.9 (5.6 to 21.3)		
rSBA-MenW-135 (PI[M1]) [N=152;29]	5495.6 (4864.5 to 6208.6)	19.8 (9.3 to 41.8)		
rSBA-MenW-135 (PI[M12]) [N=152;29]	900.8 (782.6 to 1036.8)	36.5 (17.5 to 76.1)		
rSBA-MenW-135 (PI[M24]) [N=149;25]	426.3 (364 to 499.3)	24.1 (10.8 to 54.1)		
rSBA-MenW-135 (PI[M36]) [N=147;28]	454.9 (382.7 to 540.7)	62.8 (30.4 to 129.5)		
rSBA-MenW-135 (PI[M48]) [N=138;27]	400.9 (316.6 to 507.7)	59.8 (26.5 to 135.1)		
rSBA-MenY (PRE) [N=143;31]	37.9 (27.1 to 53.1)	52.7 (25.7 to 108.3)		
rSBA-MenY (PI[M1]) [N=152;29]	2839.7 (2497.7 to 3228.4)	123.9 (66.4 to 231.4)		
rSBA-MenY (PI[M12]) [N=152;30]	776.5 (655 to 920.5)	87.8 (40.7 to 189.5)		
rSBA-MenY (PI[M24]) [N=147;30]	539.2 (444.7 to 653.7)	100 (47 to 212.5)		

rSBA-MenY (PI[M36]) [N=150;29]	581.5 (472.5 to 715.6)	220.9 (117.8 to 414.2)		
rSBA-MenY (PI[M48]) [N=138;29]	524.2 (417 to 658.9)	174.1 (74.6 to 406.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8
End point description:	
This analysis was performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe:	
Persistence Year 4	

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	29		
Units: Subjects				
rSBA-MenA (PRE) [N=155;24]	105	14		
rSBA-MenA (PI[M1]) [N=187;29]	187	29		
rSBA-MenA (PI[M12]) [N=188;28]	188	26		
rSBA-MenA (PI[M24]) [N=185;27]	185	25		
rSBA-MenA (PI[M36]) [N=182;27]	182	24		
rSBA-MenA (PI[M48]) [N=188;28]	188	24		
rSBA-MenC (PRE) [N=176;28]	112	22		
rSBA-MenC (PI[M1]) [N=187;29]	187	29		
rSBA-MenC (PI[M12]) [N=187;28]	187	28		
rSBA-MenC (PI[M24]) [N=186;29]	186	29		
rSBA-MenC (PI[M36]) [N=181;29]	181	27		
rSBA-MenC (PI[M48]) [N=188;29]	182	26		
rSBA-MenW-135 (PRE) [N=165;27]	104	19		
rSBA-MenW-135 (PI[M1]) [N=187;29]	187	29		
rSBA-MenW-135 (PI[M12]) [N=188;29]	188	29		
rSBA-MenW-135 (PI[M24]) [N=186;26]	185	22		
rSBA-MenW-135 (PI[M36]) [N=185;28]	185	22		
rSBA-MenW-135 (PI[M48]) [N=188;29]	188	22		
rSBA-MenY (PRE) [N=183;26]	123	14		
rSBA-MenY (PI[M1]) [N=187;29]	187	29		
rSBA-MenY (PI[M12]) [N=188;27]	188	26		
rSBA-MenY (PI[M24]) [N=186;29]	186	23		
rSBA-MenY (PI[M36]) [N=185;29]	185	24		
rSBA-MenY (PI[M48]) [N=188;29]	188	24		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	29		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=155;24]	59.5 (43.4 to 81.7)	58.3 (21.1 to 160.9)		
rSBA-MenA (PI[M1]) [N=187;29]	7593.9 (6848.5 to 8420.4)	2075.1 (1544.1 to 2788.7)		
rSBA-MenA (PI[M12]) [N=188;28]	2556.2 (2260.3 to 2890.9)	488.7 (246.6 to 968.3)		
rSBA-MenA (PI[M24]) [N=185;27]	1317.2 (1155.9 to 1500.9)	203.2 (112.6 to 366.5)		
rSBA-MenA (PI[M36]) [N=182;27]	1154.1 (1026.8 to 1297.2)	193.8 (102.1 to 367.9)		
rSBA-MenA (PI[M48]) [N=188;28]	1932.3 (1684.9 to 2216.1)	182.8 (85.5 to 390.9)		
rSBA-MenC (PRE) [N=176;28]	35.8 (27 to 47.4)	69.7 (34 to 142.9)		
rSBA-MenC (PI[M1]) [N=187;29]	2578.5 (2221.9 to 2992.3)	1371.7 (837.1 to 2247.7)		
rSBA-MenC (PI[M12]) [N=187;28]	510.1 (439.3 to 592.4)	444.8 (271.1 to 729.9)		
rSBA-MenC (PI[M24]) [N=186;29]	278.5 (234.3 to 330.9)	307.4 (179.2 to 527.4)		
rSBA-MenC (PI[M36]) [N=181;29]	255.7 (211.3 to 309.4)	260 (136.9 to 493.8)		

rSBA-MenC (PI[M48]) [N=188;29]	203.6 (162.9 to 254.6)	211.9 (104.8 to 428.7)		
rSBA-MenW-135 (PRE) [N=165;27]	47.4 (34.8 to 64.6)	63.7 (28.7 to 141.5)		
rSBA-MenW-135 (PI[M1]) [N=187;29]	12275.6 (11099.2 to 13576.7)	2428 (1565 to 3767.1)		
rSBA-MenW-135 (PI[M12]) [N=188;29]	3083.8 (2712.1 to 3506.3)	564.2 (366 to 869.7)		
rSBA-MenW-135 (PI[M24]) [N=186;26]	1324.2 (1150.3 to 1524.3)	149.4 (72.4 to 308.1)		
rSBA-MenW-135 (PI[M36]) [N=185;28]	1748.3 (1508.7 to 2025.9)	95.7 (44.5 to 205.8)		
rSBA-MenW-135 (PI[M48]) [N=188;29]	1807.5 (1568.9 to 2082.5)	93.4 (44.2 to 197.5)		
rSBA-MenY (PRE) [N=183;26]	56.8 (42.2 to 76.6)	34.7 (14 to 86)		
rSBA-MenY (PI[M1]) [N=187;29]	6801.4 (6206.1 to 7453.9)	1696.6 (1103.1 to 2609.4)		
rSBA-MenY (PI[M12]) [N=188;27]	2169.8 (1930.4 to 2438.9)	480.4 (260.9 to 884.9)		
rSBA-MenY (PI[M24]) [N=186;29]	1550.8 (1352.6 to 1778)	106.6 (48.5 to 234.1)		
rSBA-MenY (PI[M36]) [N=185;29]	1551.5 (1378.9 to 1745.7)	101.6 (50 to 206.5)		
rSBA-MenY (PI[M48]) [N=188;29]	1545.5 (1356.6 to 1760.6)	113.1 (55.1 to 232.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	31		
Units: Subjects				
rSBA-MenA (PI[M48]) [N=152;31]	93	0		
rSBA-MenC (PI[M48]) [N=152;31]	46	8		
rSBA-MenW-135 (PI[M48]) [N=152;31]	78	0		
rSBA-MenY (PI[M48]) [N=152;31]	84	9		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers (HPA laboratory assay)

End point title	rSBA antibodies titers (HPA laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	152	31		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI[M48]) [N=152;31]	25.7 (19.1 to 34.7)	4 (4 to 4)		
rSBA-MenC (PI[M48]) [N=152;31]	11.2 (8.3 to 15.1)	11.4 (5.2 to 25)		
rSBA-MenW-135 (PI[M48]) [N=152;31]	31.3 (21.4 to 45.6)	4 (4 to 4)		
rSBA-MenY (PI[M48]) [N=152;31]	29.9 (21.5 to 41.6)	12.5 (6 to 26.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA

	laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	29		
Units: Subjects				
rSBA-MenA (PI[M48]) [N=188;29]	157	5		
rSBA-MenC (PI[M48]) [N=188;29]	94	12		
rSBA-MenW-135 (PI[M48]) [N=187;29]	169	4		
rSBA-MenY (PI[M48]) [N=187;29]	151	2		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers (HPA laboratory assay)

End point title	rSBA antibodies titers (HPA laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	29		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI[M48]) [N=188;29]	77.5 (59.3 to 101.3)	7.3 (4.3 to 12.4)		
rSBA-MenC (PI[M48]) [N=188;29]	21.7 (16.2 to 29.1)	23.5 (9.8 to 56.3)		
rSBA-MenW-135 (PI[M48]) [N=187;29]	671.1 (500.8 to 899.4)	7.6 (4 to 14.4)		
rSBA-MenY (PI[M48]) [N=187;29]	134.8 (99.1 to 183.5)	4.7 (3.5 to 6.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8

End point description:

This analysis was performed by the GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Subjects				
rSBA-MenA (PRE) [N=41;8]	17	5		
rSBA-MenA (PI[M1]) [N=49;9]	49	3		
rSBA-MenA (PI[M12]) [N=48;6]	48	1		
rSBA-MenA (PI[M24]) [N=48;8]	48	7		
rSBA-MenA (PI[M36]) [N=45;9]	45	9		
rSBA-MenA (PI[M48]) [N=40;7]	40	7		
rSBA-MenC (PRE) [N=45;10]	15	3		
rSBA-MenC (PI[M1]) [N=48;11]	48	11		
rSBA-MenC (PI[M12]) [N=47;10]	47	10		
rSBA-MenC (PI[M24]) [N=49;11]	49	11		
rSBA-MenC (PI[M36]) [N=46;10]	46	10		
rSBA-MenC (PI[M48]) [N=43;10]	43	9		
rSBA-MenW-135 (PRE) [N=45;11]	14	3		
rSBA-MenW-135 (PI[M1]) [N=49;11]	49	3		
rSBA-MenW-135 (PI[M12]) [N=48;10]	48	7		
rSBA-MenW-135 (PI[M24]) [N=49;8]	48	4		
rSBA-MenW-135 (PI[M36]) [N=46;8]	45	5		
rSBA-MenW-135 (PI[M48]) [N=40;9]	37	5		
rSBA-MenY (PRE) [N=48;10]	30	8		
rSBA-MenY (PI[M1]) [N=49;10]	49	8		
rSBA-MenY (PI[M12]) [N=48;10]	48	8		
rSBA-MenY (PI[M24]) [N=48;11]	48	10		
rSBA-MenY (PI[M36]) [N=47;9]	47	8		
rSBA-MenY (PI[M48]) [N=40;10]	39	8		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers
End point description:	
This analysis was performed by the GSK Biologicals' laboratory	
End point type	Secondary
End point timeframe:	
Persistence Year 4	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=41;8]	22.6 (11.4 to 44.4)	45.7 (7.3 to 287.7)		
rSBA-MenA (PI[M1]) [N=49;9]	4931.9 (4071.9 to 5973.6)	16.7 (3.1 to 89.8)		
rSBA-MenA (PI[M12]) [N=48;6]	1224.2 (958.4 to 1563.8)	7.8 (1.4 to 43.7)		
rSBA-MenA (PI[M24]) [N=48;8]	668.3 (511.6 to 873)	119.5 (34.5 to 414.8)		
rSBA-MenA (PI[M36]) [N=45;9]	578.5 (445.8 to 750.7)	210.8 (128.8 to 345.2)		
rSBA-MenA (PI[M48]) [N=40;7]	782.4 (551.3 to 1110.2)	392 (192.7 to 797.6)		
rSBA-MenC (PRE) [N=45;10]	10.7 (6.7 to 17.1)	9.4 (3.2 to 27.9)		
rSBA-MenC (PI[M1]) [N=48;11]	1115.3 (878.3 to 1416.3)	536.8 (278.6 to 1034.1)		
rSBA-MenC (PI[M12]) [N=47;10]	352.4 (251.3 to 494.2)	249.3 (128.8 to 482.4)		
rSBA-MenC (PI[M24]) [N=49;11]	229.5 (169 to 311.6)	215.6 (77.6 to 599)		
rSBA-MenC (PI[M36]) [N=46;10]	472.4 (285.2 to 782.3)	229.5 (82 to 642.1)		
rSBA-MenC (PI[M48]) [N=43;10]	729.9 (468.4 to 1137.4)	332 (61.2 to 1802)		
rSBA-MenW-135 (PRE) [N=45;11]	12.8 (7.4 to 22.2)	8.4 (3.1 to 22.7)		

rSBA-MenW-135 (PI[M1]) [N=49;11]	6805 (5432.2 to 8524.7)	12.2 (3.4 to 43.8)		
rSBA-MenW-135 (PI[M12]) [N=48;10]	956.5 (710.1 to 1288.3)	49.4 (13 to 188)		
rSBA-MenW-135 (PI[M24]) [N=49;8]	408.5 (287.2 to 581.1)	25.9 (4.5 to 148.3)		
rSBA-MenW-135 (PI[M36]) [N=46;8]	486 (316.5 to 746.5)	52.9 (8.2 to 342.5)		
rSBA-MenW-135 (PI[M48]) [N=40;9]	419 (235.1 to 746.7)	31.3 (5.8 to 167.9)		
rSBA-MenY (PRE) [N=48;10]	43.7 (24.5 to 78)	99.6 (23 to 431)		
rSBA-MenY (PI[M1]) [N=49;10]	3555.6 (2928.3 to 4317.3)	138.7 (29.8 to 645.6)		
rSBA-MenY (PI[M12]) [N=48;10]	976.8 (716.8 to 1331.2)	148 (30.5 to 717.9)		
rSBA-MenY (PI[M24]) [N=48;11]	703 (500.8 to 986.9)	185.1 (59.5 to 576.3)		
rSBA-MenY (PI[M36]) [N=47;9]	684 (468.3 to 998.9)	242.2 (45.3 to 1294.5)		
rSBA-MenY (PI[M48]) [N=40;10]	601.5 (365.1 to 991)	189 (35.8 to 998.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8
End point description: This analysis was performed by the GSK Biologicals' laboratory	
End point type	Secondary
End point timeframe: Persistence Year 4	

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	13		
Units: Subjects				
rSBA-MenA (PRE) [N=81;10]	57	4		
rSBA-MenA (PI[M1]) [N=98;13]	98	13		
rSBA-MenA (PI[M12]) [N=98;13]	98	12		
rSBA-MenA (PI[M24]) [N=97;12]	97	11		
rSBA-MenA (PI[M36]) [N=95;13]	95	12		
rSBA-MenA (PI[M48]) [N=97;13]	97	11		
rSBA-MenC (PRE) [N=94;13]	65	12		
rSBA-MenC (PI[M1]) [N=98;13]	98	13		
rSBA-MenC (PI[M12]) [N=97;12]	97	12		

rSBA-MenC (PI[M24]) [N=98;13]	98	13		
rSBA-MenC (PI[M36]) [N=96;13]	96	13		
rSBA-MenC (PI[M48]) [N=97;13]	97	13		
rSBA-MenW-135 (PRE) [N=86;12]	55	10		
rSBA-MenW-135 (PI[M1]) [N=98;13]	98	13		
rSBA-MenW-135 (PI[M12]) [N=98;13]	98	13		
rSBA-MenW-135 (PI[M24]) [N=98;12]	98	10		
rSBA-MenW-135 (PI[M36]) [N=98;12]	98	10		
rSBA-MenW-135 (PI[M48]) [N=97;13]	97	11		
rSBA-MenY (PRE) [N=94;13]	62	6		
rSBA-MenY (PI[M1]) [N=98;13]	98	13		
rSBA-MenY (PI[M12]) [N=98;13]	98	12		
rSBA-MenY (PI[M24]) [N=98;13]	98	11		
rSBA-MenY (PI[M36]) [N=97;13]	97	11		
rSBA-MenY (PI[M48]) [N=97;13]	97	11		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers
End point description: This analysis was performed by the GSK Biologicals' laboratory.	
End point type	Secondary
End point timeframe: Persistence Year 4	

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	13		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=81;10]	64.3 (41.9 to 98.7)	35.7 (4.6 to 277.8)		
rSBA-MenA (PI[M1]) [N=98;13]	9195.5 (8097.2 to 10442.6)	2319 (1337.7 to 4019.9)		
rSBA-MenA (PI[M12]) [N=98;13]	3031.2 (2569.8 to 3575.5)	491 (157.4 to 1531.1)		
rSBA-MenA (PI[M24]) [N=97;12]	1641.7 (1375.5 to 1959.3)	187.9 (61.2 to 576.6)		
rSBA-MenA (PI[M36]) [N=95;13]	1318.4 (1124.3 to 1545.9)	219.9 (87 to 555.5)		

rSBA-MenA (PI[M48]) [N=97;13]	2365 (1957.2 to 2857.7)	135.4 (37.6 to 487.1)		
rSBA-MenC (PRE) [N=94;13]	44.7 (30.2 to 66.2)	114 (41.5 to 313.6)		
rSBA-MenC (PI[M1]) [N=98;13]	3604.6 (2921.3 to 4447.7)	2361.1 (1010.1 to 5518.9)		
rSBA-MenC (PI[M12]) [N=97;12]	777.4 (633.7 to 953.7)	1002 (520 to 1931)		
rSBA-MenC (PI[M24]) [N=98;13]	502.5 (402 to 628.1)	627.1 (248.2 to 1584.1)		
rSBA-MenC (PI[M36]) [N=96;13]	514.4 (409.4 to 646.4)	865.2 (475.5 to 1574)		
rSBA-MenC (PI[M48]) [N=97;13]	495.2 (386.7 to 634.1)	742.7 (356.7 to 1546.6)		
rSBA-MenW-135 (PRE) [N=86;12]	50.5 (32.4 to 78.8)	86.8 (29.7 to 253.8)		
rSBA-MenW-135 (PI[M1]) [N=98;13]	13562 (11976.3 to 15357.6)	2601 (1301.1 to 5199.6)		
rSBA-MenW-135 (PI[M12]) [N=98;13]	3794.4 (3232 to 4454.6)	462.2 (235.5 to 907.5)		
rSBA-MenW-135 (PI[M24]) [N=98;12]	1637.9 (1385.7 to 1936)	137.4 (42.5 to 443.9)		
rSBA-MenW-135 (PI[M36]) [N=98;12]	2098.3 (1783.7 to 2468.3)	96.6 (28.5 to 327.6)		
rSBA-MenW-135 (PI[M48]) [N=97;13]	2178.4 (1843.2 to 2574.4)	100.6 (37.9 to 267)		
rSBA-MenY (PRE) [N=94;13]	54.3 (35.4 to 83.2)	15.7 (5.5 to 44.7)		
rSBA-MenY (PI[M1]) [N=98;13]	7167.2 (6324.9 to 8121.8)	2085.3 (1028.6 to 4227.2)		
rSBA-MenY (PI[M12]) [N=98;13]	2502.4 (2125.3 to 2946.3)	322.7 (113.1 to 920.9)		
rSBA-MenY (PI[M24]) [N=98;13]	1907.1 (1574.2 to 2310.4)	112.3 (32 to 394)		
rSBA-MenY (PI[M36]) [N=97;13]	1670.6 (1413.6 to 1974.3)	92.2 (31.9 to 266.4)		
rSBA-MenY (PI[M48]) [N=97;13]	1736 (1430.4 to 2106.8)	83.3 (29.3 to 236.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point description:

End point type	Secondary
End point timeframe: Persistence Year 5	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Subjects				
rSBA-MenA (PI[M48]) [N=45;10]	29	0		
rSBA-MenA (PI[M60]) [N=49;11]	36	0		
rSBA-MenC (PI[M48]) [N=45;10]	44	8		
rSBA-MenC (PI[M60]) [N=49;11]	38	7		
rSBA-MenW-135 (PI[M48]) [N=45;10]	27	0		
rSBA-MenW-135 (PI[M60]) [N=49;11]	17	2		
rSBA-MenY (PI[M48]) [N=45;10]	28	3		
rSBA-MenY (PI[M60]) [N=49;11]	21	2		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers (HPA laboratory assay)

End point title	rSBA antibodies titers (HPA laboratory assay)
End point description:	

End point type	Secondary
End point timeframe: Persistence Year 5	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI[M48]) [N=45;10]	35.1 (19.4 to 63.4)	4 (4 to 4)		
rSBA-MenA (PI[M60]) [N=49;11]	37.4 (22.1 to 63.2)	4 (4 to 4)		
rSBA-MenC (PI[M48]) [N=45;10]	109.7 (62.7 to 192)	137.2 (22.6 to 831.8)		

rSBA-MenC (PI[M60]) [N=49;11]	48.9 (28.5 to 84)	26.5 (6.5 to 107.2)		
rSBA-MenW-135 (PI[M48]) [N=45;10]	50.8 (24 to 107.6)	4 (4 to 4)		
rSBA-MenW-135 (PI[M60]) [N=49;11]	18.2 (9.3 to 35.3)	7.1 (2.6 to 19.1)		
rSBA-MenY (PI[M48]) [N=45;10]	44.9 (22.6 to 89.3)	12.1 (2.3 to 63.5)		
rSBA-MenY (PI[M60]) [N=49;11]	20.6 (10.9 to 39.2)	11.7 (2.3 to 59.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point title	Number of subjects with rSBA antibodies titers ≥ 1:8 (HPA laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 5

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	13		
Units: Subjects				
rSBA-MenA (PI[M48]) [N=97;13]	86	1		
rSBA-MenA (PI[M60]) [N=98;13]	89	2		
rSBA-MenC (PI[M48]) [N=97;13]	96	12		
rSBA-MenC (PI[M60]) [N=98;13]	89	13		
rSBA-MenW-135 (PI[M48]) [N=96;13]	92	2		
rSBA-MenW-135 (PI[M60]) [N=98;13]	77	0		
rSBA-MenY (PI[M48]) [N=96;13]	85	1		
rSBA-MenY (PI[M60]) [N=98;13]	77	1		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers (HPA laboratory assay)

End point title	rSBA antibodies titers (HPA laboratory assay)

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 5

End point values	Nimenrix™ 2-11 years of age Group	Mencevax™ 2-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	13		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI[M48]) [N=97;13]	123.5 (85.4 to 178.6)	5 (3.1 to 7.9)		
rSBA-MenA (PI[M60]) [N=98;13]	141.3 (98.2 to 203.4)	4.7 (3.7 to 6)		
rSBA-MenC (PI[M48]) [N=97;13]	118.3 (86 to 162.8)	206.8 (71.7 to 596.7)		
rSBA-MenC (PI[M60]) [N=98;13]	79.7 (56 to 113.3)	128 (56.4 to 290.7)		
rSBA-MenW-135 (PI[M48]) [N=96;13]	1031.4 (731 to 1455.4)	8.4 (2.8 to 25.7)		
rSBA-MenW-135 (PI[M60]) [N=98;13]	208.5 (127.9 to 340)	4 (4 to 4)		
rSBA-MenY (PI[M48]) [N=96;13]	216.8 (147.3 to 319.1)	4.2 (3.8 to 4.7)		
rSBA-MenY (PI[M60]) [N=98;13]	143.3 (88 to 233.4)	5.5 (2.7 to 11.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	215	68		
Units: Subjects				
hSBA-MenA (PRE) [N=209;66]	3	3		
hSBA-MenA (PI[M1]) [N=211;63]	196	3		
hSBA-MenA (PI[M12]) [N=201;63]	47	3		
hSBA-MenC (PRE) [N=208;65]	3	1		
hSBA-MenC (PI[M1]) [N=215;66]	213	48		
hSBA-MenC (PI[M12]) [N=200;64]	192	34		
hSBA-MenW-135 (PRE) [N=199;62]	2	3		
hSBA-MenW-135 (PI[M1]) [N=173;56]	141	1		
hSBA-MenW-135 (PI[M12]) [N=175;62]	172	3		
hSBA-MenY (PRE) [N=182;55]	7	2		
hSBA-MenY (PI[M1]) [N=196;57]	131	3		
hSBA-MenY (PI[M12]) [N=214;68]	200	8		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 1

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	215	68		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (PRE) [N=209;66]	2 (2 to 2.1)	2.2 (2 to 2.4)		
hSBA-MenA (PI[M1]) [N=211;63]	57.6 (47.9 to 69.3)	2.2 (1.9 to 2.5)		
hSBA-MenA (PI[M12]) [N=201;63]	3.6 (3.1 to 4.2)	2.2 (2 to 2.4)		
hSBA-MenC (PRE) [N=208;65]	2.1 (2 to 2.2)	2.1 (1.9 to 2.3)		
hSBA-MenC (PI[M1]) [N=215;66]	187 (161.6 to 216.5)	22 (14.3 to 33.8)		
hSBA-MenC (PI[M12]) [N=200;64]	88.7 (73.8 to 106.5)	12.2 (7.6 to 19.5)		
hSBA-MenW-135 (PRE) [N=199;62]	2.1 (2 to 2.2)	2.2 (2 to 2.4)		

hSBA-MenW-135 (PI[M1]) [N=173;56]	38.5 (29.3 to 50.5)	2.1 (2 to 2.2)		
hSBA-MenW-135 (PI[M12]) [N=175;62]	225.1 (184.5 to 274.7)	2.4 (1.9 to 3)		
hSBA-MenY (PRE) [N=182;55]	2.2 (2 to 2.3)	2.1 (2 to 2.2)		
hSBA-MenY (PI[M1]) [N=196;57]	23.8 (18.1 to 31.4)	2.5 (1.9 to 3.2)		
hSBA-MenY (PI[M12]) [N=214;68]	105.1 (85.2 to 129.7)	3.2 (2.3 to 4.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4
End point description:	
End point type	Secondary
End point timeframe:	
Persistence Year 2	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	51		
Units: Subjects				
hSBA-MenA (PRE) [N=193;51]	3	3		
hSBA-MenA (PI[M1]) [N=194;48]	180	2		
hSBA-MenA (PI[M24]) [N=180;50]	73	6		
hSBA-MenC (PRE) [N=192;49]	2	1		
hSBA-MenC (PI[M1]) [N=198;50]	196	38		
hSBA-MenC (PI[M24]) [N=191;51]	179	28		
hSBA-MenW-135 (PRE) [N=183;47]	2	2		
hSBA-MenW-135 (PI[M1]) [N=158;45]	130	1		
hSBA-MenW-135 (PI[M24]) [N=178;51]	171	5		
hSBA-MenY (PRE) [N=168;42]	6	2		
hSBA-MenY (PI[M1]) [N=181;44]	121	3		
hSBA-MenY (PI[M24]) [N=173;43]	157	13		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 2

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	51		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (PRE) [N=193;51]	2 (2 to 2.1)	2.2 (2 to 2.5)		
hSBA-MenA (PI[M1]) [N=194;48]	58.8 (48.5 to 71.3)	2.2 (1.9 to 2.7)		
hSBA-MenA (PI[M24]) [N=180;50]	5.1 (4.2 to 6.1)	2.3 (2 to 2.5)		
hSBA-MenC (PRE) [N=192;49]	2.1 (2 to 2.1)	2.1 (1.9 to 2.4)		
hSBA-MenC (PI[M1]) [N=198;50]	185.4 (159.3 to 215.9)	26.7 (16.1 to 44.3)		
hSBA-MenC (PI[M24]) [N=191;51]	55.6 (45.1 to 68.5)	11.8 (6.8 to 20.6)		
hSBA-MenW-135 (PRE) [N=183;47]	2.1 (2 to 2.2)	2.1 (2 to 2.3)		
hSBA-MenW-135 (PI[M1]) [N=158;45]	38.7 (29.2 to 51.2)	2.1 (1.9 to 2.2)		
hSBA-MenW-135 (PI[M24]) [N=178;51]	111.4 (90.9 to 136.5)	2.9 (2.1 to 4)		
hSBA-MenY (PRE) [N=168;42]	2.1 (2 to 2.3)	2.1 (2 to 2.2)		
hSBA-MenY (PI[M1]) [N=181;44]	23.1 (17.4 to 30.8)	2.6 (1.9 to 3.7)		
hSBA-MenY (PI[M24]) [N=173;43]	72.5 (57 to 92.4)	5 (3.1 to 7.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 3

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	37		
Units: Subjects				
hSBA-MenA (PRE) [N=172;37]	1	3		
hSBA-MenA (PI[M1]) [N=172;36]	159	3		
hSBA-MenA (PI[M36]) [N=170;36]	37	2		
hSBA-MenC (PRE) [N=170;35]	2	0		
hSBA-MenC (PI[M1]) [N=176;36]	174	31		
hSBA-MenC (PI[M36]) [N=166;33]	147	25		
hSBA-MenW-135 (PRE) [N=163;34]	2	2		
hSBA-MenW-135 (PI[M1]) [N=138;33]	112	1		
hSBA-MenW-135 (PI[M36]) [N=164;35]	131	3		
hSBA-MenY (PRE) [N=149;31]	5	2		
hSBA-MenY (PI[M1]) [N=161;34]	110	3		
hSBA-MenY (PI[M36]) [N=159;33]	117	9		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 3

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	176	37		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (PRE) [N=172;37]	2 (2 to 2)	2.3 (2 to 2.7)		
hSBA-MenA (PI[M1]) [N=172;36]	56.9 (46.4 to 69.9)	2.4 (1.9 to 3)		
hSBA-MenA (PI[M36]) [N=170;36]	3.3 (2.8 to 3.8)	2.2 (1.9 to 2.6)		
hSBA-MenC (PRE) [N=170;35]	2.1 (2 to 2.2)	2 (2 to 2)		
hSBA-MenC (PI[M1]) [N=176;36]	182.7 (154.6 to 215.8)	44.1 (25.2 to 77.3)		
hSBA-MenC (PI[M36]) [N=166;33]	65.1 (49.6 to 85.5)	32.5 (16 to 65.9)		
hSBA-MenW-135 (PRE) [N=163;34]	2.1 (2 to 2.2)	2.2 (1.9 to 2.6)		

hSBA-MenW-135 (PI[M1]) [N=138;33]	39.1 (28.8 to 53.1)	2.1 (1.9 to 2.3)		
hSBA-MenW-135 (PI[M36]) [N=164;35]	40.8 (31.1 to 53.6)	3 (1.9 to 4.7)		
hSBA-MenY (PRE) [N=149;31]	2.1 (2 to 2.2)	2.1 (1.9 to 2.3)		
hSBA-MenY (PI[M1]) [N=161;34]	24.8 (18.3 to 33.5)	2.8 (1.8 to 4.4)		
hSBA-MenY (PI[M36]) [N=159;33]	37.3 (27.2 to 51.2)	6 (3 to 11.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4
End point description:	
End point type	Secondary
End point timeframe:	
Persistence Year 4	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	31		
Units: Subjects				
hSBA-MenA (PRE) [N=148;30]	0	2		
hSBA-MenA (PI[M1]) [N=148;30]	137	1		
hSBA-MenA (PI[M48]) [N=140;31]	57	8		
hSBA-MenC (PRE) [N=146;28]	2	0		
hSBA-MenC (PI[M1]) [N=151;29]	149	25		
hSBA-MenC (PI[M48]) [N=147;31]	126	24		
hSBA-MenW-135 (PRE) [N=141;27]	2	1		
hSBA-MenW-135 (PI[M1]) [N=119;28]	100	1		
hSBA-MenW-135 (PI[M48]) [N=143;31]	117	3		
hSBA-MenY (PRE) [N=127;26]	5	1		
hSBA-MenY (PI[M1]) [N=139;28]	93	2		
hSBA-MenY (PI[M48]) [N=129;26]	100	12		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 4

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	31		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (PRE) [N=148;30]	2 (2 to 2)	2.2 (1.9 to 2.5)		
hSBA-MenA (PI[M1]) [N=148;30]	57.7 (46.1 to 72.1)	2.3 (1.8 to 2.9)		
hSBA-MenA (PI[M48]) [N=140;31]	6 (4.7 to 7.7)	3.1 (2.3 to 4)		
hSBA-MenC (PRE) [N=146;28]	2.1 (2 to 2.2)	2 (2 to 2)		
hSBA-MenC (PI[M1]) [N=151;29]	192.5 (160.7 to 230.7)	45 (23.3 to 86.9)		
hSBA-MenC (PI[M48]) [N=147;31]	51.4 (36.9 to 71.7)	32.4 (14.8 to 71.1)		
hSBA-MenW-135 (PRE) [N=141;27]	2.1 (2 to 2.2)	2.1 (1.9 to 2.3)		
hSBA-MenW-135 (PI[M1]) [N=119;28]	41.7 (30.4 to 57.3)	2.1 (1.9 to 2.3)		
hSBA-MenW-135 (PI[M48]) [N=143;31]	48.3 (36.2 to 64.4)	2.8 (1.9 to 4.2)		
hSBA-MenY (PRE) [N=127;26]	2.1 (2 to 2.2)	2.1 (1.9 to 2.3)		
hSBA-MenY (PI[M1]) [N=139;28]	22.5 (16.3 to 31.1)	2.6 (1.7 to 4.1)		
hSBA-MenY (PI[M48]) [N=129;26]	42.1 (30.6 to 58.1)	13.5 (5.6 to 32.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4

End point description:

End point type	Secondary

End point timeframe:

Persistence Year 5

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Subjects				
hSBA-MenA (PRE) [N=47;11]	0	0		
hSBA-MenA (PI[M1]) [N=49;11]	48	0		
hSBA-MenA (PI[M60]) [N=45;11]	16	3		
hSBA-MenC (PRE) [N=45;10]	0	0		
hSBA-MenC (PI[M1]) [N=48;11]	48	9		
hSBA-MenC (PI[M60]) [N=48;11]	45	10		
hSBA-MenW-135 (PRE) [N=44;9]	1	1		
hSBA-MenW-135 (PI[M1]) [N=41;11]	37	0		
hSBA-MenW-135 (PI[M60]) [N=46;9]	38	2		
hSBA-MenY (PRE) [N=45;8]	2	2		
hSBA-MenY (PI[M1]) [N=48;10]	40	0		
hSBA-MenY (PI[M60]) [N=45;10]	36	4		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers
End point description:	
End point type	Secondary
End point timeframe:	
Persistence Year 5	

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	11		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA (PRE) [N=47;11]	2 (2 to 2)	2 (2 to 2)		
hSBA-MenA (PI[M1]) [N=49;11]	78.5 (55.7 to 110.4)	2 (2 to 2)		
hSBA-MenA (PI[M60]) [N=45;11]	5.2 (3.4 to 7.8)	3.6 (1.8 to 7.2)		
hSBA-MenC (PRE) [N=45;10]	2 (2 to 2)	2 (2 to 2)		
hSBA-MenC (PI[M1]) [N=48;11]	252 (193.2 to 328.6)	38.7 (10.5 to 142.9)		
hSBA-MenC (PI[M60]) [N=48;11]	216.5 (123.6 to 379.1)	108.7 (21.2 to 557.2)		
hSBA-MenW-135 (PRE) [N=44;9]	2.2 (1.8 to 2.5)	2.3 (1.6 to 3.3)		

hSBA-MenW-135 (PI[M1]) [N=41;11]	81.3 (45.4 to 145.7)	2 (2 to 2)		
hSBA-MenW-135 (PI[M60]) [N=46;9]	59.7 (35.1 to 101.4)	5.1 (1.2 to 20.9)		
hSBA-MenY (PRE) [N=45;8]	2.1 (1.9 to 2.4)	2.6 (1.7 to 3.8)		
hSBA-MenY (PI[M1]) [N=48;10]	46.1 (27.4 to 77.5)	2 (2 to 2)		
hSBA-MenY (PI[M60]) [N=45;10]	70.6 (38.7 to 128.8)	11.6 (2.2 to 59.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) (1 - < 2 years of age and 2 - < 6 years of age groups) and 50 mm (6 - < 11 years of age groups) of injection site, respectively. Relationship analysis was not performed.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0-3) follow-up period

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-6 years of age Group	Nimenrix™ 6-11 years of age Group	Meningitec™ 1-2 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	228	113	117	73
Units: Subjects				
Any Pain	76	51	84	20
Grade 3 Pain	3	2	7	0
Any Redness	84	44	53	24
Grade 3 Redness	8	12	19	1
Any Swelling	36	29	42	11
Grade 3 Swelling	3	9	14	0

End point values	Mencevax™ 2-6 years of age Group	Mencevax™ 6-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	39		
Units: Subjects				
Any Pain	28	32		
Grade 3 Pain	1	1		

Any Redness	8	15		
Grade 3 Redness	0	0		
Any Swelling	3	6		
Grade 3 Swelling	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms

End point title	Number of subjects with solicited general symptoms

End point description:

Assessed solicited general symptoms were drowsiness, fever [defined as rectal temperature equal to or above 38.0 degrees Celsius (°C)], irritability and loss of appetite. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 40.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0-3) follow-up period

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-6 years of age Group	Nimenrix™ 6-11 years of age Group	Meningitec™ 1-2 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	228	113	117	73
Units: Subjects				
Any Drowsiness	63	30	45	25
Grade 3 Drowsiness	2	0	1	0
Related Drowsiness	61	29	45	25
Any Fever	36	7	11	9
Grade 3 Fever >40.0˚C	2	0	0	0
Related Fever	32	7	11	9
Any Irritability	88	18	23	29
Grade 3 Irritability	2	0	3	0
Related Irritability	85	18	21	29
Any Loss of appetite	54	16	31	17
Grade 3 Loss of appetite	2	0	1	0
Related Loss of appetite	52	16	29	17

End point values	Mencevax™ 2-6 years of age Group	Mencevax™ 6-11 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	39		
Units: Subjects				
Any Drowsiness	5	8		

Grade 3 Drowsiness	0	0		
Related Drowsiness	5	8		
Any Fever	2	1		
Grade 3 Fever >40.0°C	0	0		
Related Fever	2	0		
Any Irritability	11	5		
Grade 3 Irritability	0	1		
Related Irritability	10	4		
Any Loss of appetite	6	6		
Grade 3 Loss of appetite	0	0		
Related Loss of appetite	5	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rash

End point title	Number of subjects with rash[13]

End point description:

End point type	Secondary

End point timeframe:

From administration of the vaccine dose until 6 months later

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	229	75	231	78
Units: Subjects				
At least one symptom	10	6	9	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with New Onset of Chronic Illnesses (NOCIs)

End point title	Number of subjects with New Onset of Chronic Illnesses (NOCIs)[14]

End point description:

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

End point type	Secondary

End point timeframe:

From administration of the vaccine dose until 6 months later

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	229	75	231	78
Units: Subjects				
At least one symptom	1	0	2	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Adverse Events (AEs) resulting in an Emergency Room (ER) visit

End point title	Number of subjects with Adverse Events (AEs) resulting in an Emergency Room (ER) visit[15]

End point description:

End point type	Secondary

End point timeframe:

From administration of the vaccine dose until 6 months later

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	229	75	231	78
Units: Subjects				
At least one symptom	21	8	15	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs

End point title	Number of subjects with unsolicited AEs[16]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) post-vaccination period

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	229	75	231	78
Units: Subjects				
Any AE(s)	121	38	83	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Serious Adverse Events (SAEs)

End point title	Number of subjects with Serious Adverse Events (SAEs)[17]

End point description:

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:

Up to 6 Months after vaccination

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	229	75	231	78
Units: Subjects				
Any SAE(s)	5	7	2	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAE(s)

End point title	Number of subjects with SAE(s)

End point description:

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 6 Months after vaccination up to Year 1

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group	Mencevax™ 2-11 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	221	71	78
Units: Subjects				
Any SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAE(s)

End point title	Number of subjects with SAE(s)

End point description:

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 6 Months after vaccination up to Year 2

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group	Mencevax™ 2-11 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	208	215	53	61
Units: Subjects				
Any SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAE(s)

End point title	Number of subjects with SAE(s)

End point description:

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 6 Months following vaccination up to Year 3

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group	Mencevax™ 2-11 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	185	201	38	38
Units: Subjects				
Any SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAE(s)

End point title	Number of subjects with SAE(s)

End point description:

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 6 Months following vaccination up to Year 4

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group	Mencevax™ 2-11 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	165	192	34	32
Units: Subjects				
Any SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAE(s)

End point title	Number of subjects with SAE(s)

End point description:

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 6 Months following vaccination up to Year 5

End point values	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group	Mencevax™ 2-11 years of age Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	99	12	13
Units: Subjects				
Any SAE(s)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL and ≥ 2.0 µg/mL

End point title	Number of subjects with anti-PS antibodies concentrations ≥ 0.3 µg/mL and ≥ 2.0 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	75		
Units: Subjects				
Anti-PSA ≥0.3µg/mL, PRE [N=218,75]	29	12		
Anti-PSA ≥0.3µg/mL, PI(M1) [N=224,74]	224	73		
Anti-PSA ≥2.0µg/mL, PRE [N=218,75]	9	2		
Anti-PSA ≥2.0µg/mL, PI(M1) [N=224,74]	224	68		
Anti-PSC ≥0.3µg/mL , PRE [N=225,74]	28	6		
Anti-PSC ≥0.3µg/mL, PI(M1) [N=224,74]	224	74		
Anti-PSC ≥2.0µg/mL, PRE [N=225,74]	9	2		
Anti-PSC ≥2.0µg/mL, PI(M1) [N=224,74]	223	71		
Anti-PSW-135 ≥0.3µg/mL , PRE [N=225,75]	3	1		
Anti-PSW-135 ≥0.3µg/mL , PI(M1) [N=224,74]	224	72		
Anti-PSW-135 ≥2.0µg/mL , PRE [N=225,75]	0	0		
Anti-PSW-135 ≥2.0µg/mL , PI(M1) [N=224,74]	197	54		
Anti-PSY ≥0.3µg/mL, PRE [N=224,74]	6	0		
Anti-PSY ≥0.3µg/mL, PI(M1) [N=225,74]	225	72		
Anti-PSY ≥2.0µg/mL, PRE [N=224,74]	1	0		
Anti-PSY ≥2.0µg/mL, PI(M1) [N=225,74]	217	71		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PS antibodies concentrations

End point title	Anti-PS antibodies concentrations

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month post vaccination [PI(M1)]

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	75		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, PRE [N=218,75]	0.19 (0.17 to 0.21)	0.2 (0.16 to 0.23)		
Anti-PSA, PI(M1) [N=224,74]	36.35 (32.3 to 40.91)	10.34 (7.79 to 13.72)		
Anti-PSC, PRE [N=225,74]	0.2 (0.18 to 0.22)	0.19 (0.15 to 0.22)		
Anti-PSC, PI(M1) [N=224,74]	13.33 (11.75 to 15.12)	14.53 (11.13 to 18.95)		
Anti-PSW-135, PRE [N=225,75]	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.16)		
Anti-PSW-135, PI(M1) [N=224,74]	6.35 (5.53 to 7.29)	4.62 (3.37 to 6.35)		
Anti-PSY, PRE [N=224,74]	0.16 (0.15 to 0.16)	0.15 (0.15 to 0.15)		
Anti-PSY, PI(M1) [N=225,74]	11.35 (10.01 to 12.87)	15.45 (11.42 to 20.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-TT antibody concentrations ≥ 0.1 IU/mL

End point title	Number of subjects with anti-TT antibody concentrations ≥ 0.1 IU/mL

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	7		
Units: Subjects				
Anti-TT, PRE [N=19,4]	19	4		
Anti-TT, PI(M1) [N=32,7]	32	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-TT antibody concentrations

End point title	Anti-TT antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

End point values	Nimenrix™ 2-11 years of age Primary Phase Group	Mencevax™ 2-11 years of age Primary Phase Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	7		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-TT, PRE [N=19,4]	1.541 (0.856 to 2.775)	2.103 (0.129 to 34.398)		
Anti-TT, PI(M1) [N=32,7]	20.951 (14.656 to 29.949)	1.74 (0.536 to 5.642)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA antibodies titers ≥ 1:4

End point title	Number of subjects with hSBA antibodies titers ≥ 1:4[18]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	221	68		
Units: Subjects				
hSBA-MenA, PRE [N=215,68]	3	3		
hBA-MenA, PI(M1) [N=217,65]	203	4		
hSBA-MenC, PRE [N=214,67]	3	1		
hSBA-MenC, PI(M1) [N=221,68]	219	49		
hSBA-MenW-135, PRE [N=205,64]	2	3		
hSBA-MenW-135, PI(M1) [N=177,58]	145	1		
hSBA-MenY, PRE [N=189,57]	7	2		
hSBA-MenY, PI(M1) [N=201,59]	135	3		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA antibodies titers

End point title	hSBA antibodies titers[19]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	221	68		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA, PRE [N=215,68]	2 (2 to 2.1)	2.2 (2 to 2.3)		
hBA-MenA, PI(M1) [N=217,65]	59 (49.3 to 70.6)	2.3 (2 to 2.6)		
hSBA-MenC, PRE [N=214,67]	2.1 (2 to 2.2)	2.1 (1.9 to 2.3)		
hSBA-MenC, PI(M1) [N=221,68]	190 (164.7 to 219.2)	21.2 (13.9 to 32.3)		
hSBA-MenW-135, PRE [N=205,64]	2.1 (2 to 2.1)	2.2 (2 to 2.4)		
hSBA-MenW-135, PI(M1) [N=177,58]	38.8 (29.7 to 50.6)	2 (2 to 2.1)		
hSBA-MenY, PRE [N=189,57]	2.2 (2 to 2.3)	2.1 (2 to 2.2)		

hSBA-MenY, PI(M1) [N=201,59]	24.4 (18.6 to 32.1)	2.4 (1.9 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA antibodies titers ≥ 1:128

End point title	Number of subjects with rSBA antibodies titers ≥ 1:128[20]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	68		
Units: Subjects				
rSBA-MenA, PRE [N=191,65]	59	20		
rSBA-MenA, PI(M1) [N=222,63]	222	16		
rSBA-MenC, PRE [N=203,61]	29	4		
rSBA-MenC, PI(M1) [N=220,68]	218	56		
rSBA-MenW-135, PRE [N=208,62]	38	16		
rSBA-MenW-135, PI(M1) [N=222,63]	222	18		
rSBA-MenY, PRE [N=208,67]	77	28		
rSBA-MenY, PI(M1) [N=222,66]	221	31		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibodies titers

End point title	rSBA antibodies titers[21]

End point description:

End point type	Secondary

End point timeframe:

Prior to (PRE) and one month after vaccination [PI(M1)]

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	Nimenrix™ 1-2 years of age Group	Meningitec™ 1-2 years of age Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	68		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, PRE [N=191,65]	21.6 (16.1 to 29)	20.2 (12.1 to 33.8)		
rSBA-MenA, PI(M1) [N=222,63]	3706.5 (3327.2 to 4128.9)	17.1 (10.1 to 29)		
rSBA-MenC, PRE [N=203,61]	13.9 (11 to 17.5)	9.7 (6.8 to 13.9)		
rSBA-MenC, PI(M1) [N=220,68]	878.7 (779.4 to 990.7)	415 (296.9 to 580)		
rSBA-MenW-135, PRE [N=208,62]	11.3 (8.9 to 14.3)	16.5 (10.2 to 26.7)		
rSBA-MenW-135, PI(M1) [N=222,63]	5394.6 (4869.9 to 5975.7)	20.3 (12.5 to 33.2)		
rSBA-MenY, PRE [N=208,67]	33.8 (25.6 to 44.6)	45.3 (27 to 75.8)		
rSBA-MenY, PI(M1) [N=222,66]	2823.8 (2529 to 3153.1)	77.1 (46.3 to 128.2)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day (Day 0-3) follow-up vaccination period, Unsolicited AEs during the 31-day (Days 0-30) post-vaccination period, SAEs during the entire study periods.

Adverse event reporting additional description:

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

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.1

Reporting groups

Reporting group title	Nimenrix™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Nimenrix™ 2-11 years of age Group
Reporting group description: -	
Reporting group title	Meningitec™ 1-2 years of age Group
Reporting group description: -	
Reporting group title	Mencevax™ 2-11 years of age Group
Reporting group description: -	

Serious adverse events	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 229 (2.18%)	2 / 231 (0.87%)	7 / 75 (9.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	1 / 229 (0.44%)	0 / 231 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 231 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Testicular torsion			

subjects affected / exposed	0 / 229 (0.00%)	0 / 231 (0.00%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	1 / 229 (0.44%)	0 / 231 (0.00%)	2 / 75 (2.67%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 229 (0.44%)	1 / 231 (0.43%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 231 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 231 (0.00%)	1 / 75 (1.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 229 (0.00%)	0 / 231 (0.00%)	2 / 75 (2.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 231 (0.43%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	0 / 229 (0.00%)	1 / 231 (0.43%)	0 / 75 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Mencevax™ 2-11 years of age Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 78 (1.28%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Lower limb fracture			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Testicular torsion			
subjects affected / exposed	1 / 78 (1.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastroenteritis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyperglycemia			
subjects affected / exposed	0 / 78 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Nimenrix™ 1-2 years of age Group	Nimenrix™ 2-11 years of age Group	Meningitec™ 1-2 years of age Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	121 / 229 (52.84%)	135 / 231 (58.44%)	38 / 75 (50.67%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	76 / 228 (33.33%)	135 / 230 (58.70%)	20 / 73 (27.40%)
occurrences (all)	76	135	20
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	84 / 228 (36.84%)	97 / 230 (42.17%)	24 / 73 (32.88%)
occurrences (all)	84	97	24
Swelling			
alternative assessment type: Systematic			

subjects affected / exposed[3]	36 / 228 (15.79%)	71 / 230 (30.87%)	11 / 73 (15.07%)
occurrences (all)	36	71	11
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[4]	63 / 228 (27.63%)	30 / 230 (13.04%)	25 / 73 (34.25%)
occurrences (all)	63	30	25
Fever (Rectally)			
alternative assessment type: Systematic			
subjects affected / exposed[5]	36 / 228 (15.79%)	18 / 230 (7.83%)	9 / 73 (12.33%)
occurrences (all)	36	18	9
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[6]	88 / 228 (38.60%)	18 / 230 (7.83%)	29 / 73 (39.73%)
occurrences (all)	88	18	29
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[7]	54 / 228 (23.68%)	16 / 230 (6.96%)	17 / 73 (23.29%)
occurrences (all)	54	16	17
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed[8]	0 / 228 (0.00%)	45 / 117 (38.46%)	0 / 73 (0.00%)
occurrences (all)	0	45	0
Gastrointestinal			
alternative assessment type: Systematic			
subjects affected / exposed[9]	0 / 228 (0.00%)	23 / 117 (19.66%)	0 / 73 (0.00%)
occurrences (all)	0	23	0
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[10]	0 / 228 (0.00%)	31 / 117 (26.50%)	0 / 75 (0.00%)
occurrences (all)	0	31	0
Pyrexia			
subjects affected / exposed	15 / 229 (6.55%)	12 / 231 (5.19%)	10 / 75 (13.33%)
occurrences (all)	15	12	10
Gastrointestinal disorders			

Diarrhea			
subjects affected / exposed	11 / 229 (4.80%)	5 / 231 (2.16%)	7 / 75 (9.33%)
occurrences (all)	11	5	7
Teething			
subjects affected / exposed	5 / 229 (2.18%)	0 / 231 (0.00%)	4 / 75 (5.33%)
occurrences (all)	5	0	4
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	18 / 229 (7.86%)	5 / 231 (2.16%)	5 / 75 (6.67%)
occurrences (all)	18	5	5
Infections and infestations			
Otitis media			
subjects affected / exposed	16 / 229 (6.99%)	12 / 231 (5.19%)	9 / 75 (12.00%)
occurrences (all)	16	12	9
Rhinitis			
subjects affected / exposed	19 / 229 (8.30%)	9 / 231 (3.90%)	4 / 75 (5.33%)
occurrences (all)	19	9	4
Upper respiratory tract infection			
subjects affected / exposed	14 / 229 (6.11%)	10 / 231 (4.33%)	8 / 75 (10.67%)
occurrences (all)	14	10	8
Gastroenteritis			
subjects affected / exposed	12 / 229 (5.24%)	4 / 231 (1.73%)	1 / 75 (1.33%)
occurrences (all)	12	4	1

Non-serious adverse events	Mencevax™ 2-11 years of age Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	60 / 78 (76.92%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	60 / 78 (76.92%)		
occurrences (all)	60		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	23 / 78 (29.49%)		
occurrences (all)	23		

Swelling				
alternative assessment type: Systematic				
subjects affected / exposed[3]	9 / 78 (11.54%)			
occurrences (all)	9			
Drowsiness				
alternative assessment type: Systematic				
subjects affected / exposed[4]	5 / 78 (6.41%)			
occurrences (all)	5			
Fever (Rectally)				
alternative assessment type: Systematic				
subjects affected / exposed[5]	3 / 78 (3.85%)			
occurrences (all)	3			
Irritability				
alternative assessment type: Systematic				
subjects affected / exposed[6]	11 / 78 (14.10%)			
occurrences (all)	11			
Loss of appetite				
alternative assessment type: Systematic				
subjects affected / exposed[7]	6 / 78 (7.69%)			
occurrences (all)	6			
Fatigue				
alternative assessment type: Systematic				
subjects affected / exposed[8]	8 / 39 (20.51%)			
occurrences (all)	8			
Gastrointestinal				
alternative assessment type: Systematic				
subjects affected / exposed[9]	5 / 39 (12.82%)			
occurrences (all)	5			
Headache				
alternative assessment type: Systematic				
subjects affected / exposed[10]	6 / 39 (15.38%)			
occurrences (all)	6			
Pyrexia				

subjects affected / exposed occurrences (all)	2 / 78 (2.56%) 2		
Gastrointestinal disorders Diarrhea subjects affected / exposed occurrences (all) Teething subjects affected / exposed occurrences (all)	 1 / 78 (1.28%) 1 0 / 78 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	 3 / 78 (3.85%) 3		
Infections and infestations Otitis media subjects affected / exposed occurrences (all) Rhinitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Gastroenteritis subjects affected / exposed occurrences (all)	 1 / 78 (1.28%) 1 0 / 78 (0.00%) 0 4 / 78 (5.13%) 4 0 / 78 (0.00%) 0		

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.
[8] - 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.
[9] - 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.
[10] - 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
10 January 2012	To support the data obtained by serum bactericidal assay (SBA) testing, antibody concentrations against meningococcal polysaccharides (PSs) were planned to be assessed by enzyme-linked immunosorbent assay (ELISA). The ELISA testing was performed prior to and one month after vaccination, and one and two years after vaccine administration, but the sponsor decided not to perform the ELISA testing at three, four and five years after vaccine administration for the following reasons: •the World Health Organization (WHO) considers SBA the primary means of assessing immune response to meningococcal conjugate vaccines [WHO, 2006; WHO, 1999]. •circulating bactericidal antibodies are more critical for persistent protection against meningococcal disease than non-functional antibodies against meningococcal PSs [Centers for Disease Control (CDC), 2011; WHO, 2006]. Although antibody concentrations will not be determined by ELISA at three, four and five years after vaccine administration, all subjects will be informed of their SBA antibody titers at each immunogenicity time point when statistical analyses at that time point have been completed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported