Clinical trial results:
A phase IIIB open, multicountry, randomized, controlled study to demonstrate the non-inferiority of the immune response of GSK Biologicals' meningococcal serogroup A, C, W-135 and Y conjugate vaccine (MenACWY-TT)* when given intramuscularly at 2, 4 and 12 months of age or given at 2, 3, 4 and 12 months of age compared to two licensed MenC conjugate vaccine given intramuscularly at 2, 4 and 12 months of age.
*MenACWY-TT has been divested to Pfizer as of 01 October 2015.

Summary

EudraCT number	2009-016841-24
Trial protocol	ES DE EE
Global end of trial date	10 September 2013

Results information

Result version number	v3 (current)
This version publication date	20 January 2021
First version publication date	05 June 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	113369

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01144663
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000429-PIP01-08
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 August 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 September 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To demonstrate at 5 months of age (Visit 4) the non-inferiority of the 3-dose schedule of MenACWY-TT vaccine compared to the 2- dose schedule of the MenC-CRM or MenC-TT vaccines in terms of percentage of subjects with post-primary vaccination rSBA-MenC antibody titre ≥ 1:8.
- To demonstrate at 5 months of age (Visit 4) the non-inferiority of the 2-dose schedule of MenACWY-TT vaccine compared to the 2- dose schedule of the MenC-CRM or MenC-TT vaccines in terms of percentage of subjects with post-primary vaccination rSBA-MenC antibody titre ≥ 1:8.
- To demonstrate at 5 months of age (Visit 4) the immunogenicity of the 3-dose and the 2-dose schedule for MenACWY-TT for serogroups A, W-135 and Y.

Protection of trial subjects:

All subjects were supervised for 30 minutes 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	01 July 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	5 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 1559
Country: Number of subjects enrolled	Estonia: 34
Country: Number of subjects enrolled	Germany: 502
Worldwide total number of subjects	2095
EEA total number of subjects	2095

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)	2095
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix 3 Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	GSK134612A MenACWY-TT, GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3, 4 and 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3, 4 and 12 months of age.

Arm title	Nimenrix 2 Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of

Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	GSK134612A, MenACWY-TT, GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Arm title	Menjugate Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Active comparator
Investigational medicinal product name	Menjugate®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Arm title	NeisVac-C Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Active comparator
Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Number of subjects in period 1	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group
Started	528	524	516
Completed	508	517	508
Not completed	20	7	8
Consent withdrawn by subject	9	5	3
Adverse event, non-fatal	1	-	-
Serious adverse event, fatal	2	-	1
Not specified	-	1	-
Migrated/moved from study area	4	1	2
Lost to follow-up	2	-	1
Protocol deviation	2	-	1

Number of subjects in period 1	NeisVac-C Group
Started	527
Completed	509
Not completed	18

Consent withdrawn by subject	10
Adverse event, non-fatal	1
Serious adverse event, fatal	-
Not specified	2
Migrated/moved from study area	3
Lost to follow-up	2
Protocol deviation	-

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix 3 Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	GSK134612A MenACWY-TT, GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 3, 4 and 12 months of age.

Arm title	Nimenrix 2 Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Nimenrix™
Investigational medicinal product code	
Other name	GSK134612A, MenACWY-TT, GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Arm title	Menjugate Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Active comparator
Investigational medicinal product name	Menjugate®
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Arm title	NeisVac-C Group

Arm description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Arm type	Active comparator
Investigational medicinal product name	NeisVac-C™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2 and 4 months of age and 1 booster dose at 12 months of age.

Investigational medicinal product name	Infanrix™ hexa
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Investigational medicinal product name	Synflorix™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose intramuscular injection at 2, 4 and 12 months of age.

Number of subjects in period 2[1]	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group
Started	497	511	503
Completed	494	509	498
Not completed	3	2	5
Consent withdrawn by subject	-	-	1
Migrated/moved from study area	1	1	1
Lost to follow-up	2	1	3

Number of subjects in period 2[1]	NeisVac-C Group
Started	506

Completed	505
Not completed	1
Consent withdrawn by subject	1
Migrated/moved from study area	-
Lost to follow-up	-

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.

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix 3 Group
Reporting group description:	
Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.	
Reporting group title	Nimenrix 2 Group
Reporting group description:	
Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.	
Reporting group title	Menjugate Group
Reporting group description:	
Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.	
Reporting group title	NeisVac-C Group
Reporting group description:	
Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.	

Reporting group values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group
Number of subjects	528	524	516
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	528	524	516
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Weeks			
arithmetic mean	8.7	8.6	8.7
standard deviation	± 1.54	± 1.52	± 1.53
Sex: Female, Male Units: Participants			
Female	255	273	264
Male	273	251	252

Race/Ethnicity, Customized Units: Subjects			
African heritage/African American	5	4	6
American Indian or Alaskan Native	1	4	4
Asian-Central/South Asian heritage	1	1	0
Asian-East Asian heritage	0	1	1
Asian-South East Asian heritage	1	0	0
Native Hawaiian or other Pacific Islander	0	0	1
White-Arabic/North African heritage	12	8	10
White-Caucasian/European heritage	500	497	486
Not specified	8	9	8

Reporting group values	NeisVac-C Group	Total	
Number of subjects	527	2095	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	527	2095	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: Weeks			
arithmetic mean	8.6		
standard deviation	± 1.49	-	
Sex: Female, Male Units: Participants			
Female	251	1043	
Male	276	1052	
Race/Ethnicity, Customized Units: Subjects			
African heritage/African American	1	16	
American Indian or Alaskan Native	2	11	
Asian-Central/South Asian heritage	0	2	
Asian-East Asian heritage	1	3	
Asian-South East Asian heritage	0	1	
Native Hawaiian or other Pacific Islander	0	1	
White-Arabic/North African heritage	21	51	
White-Caucasian/European heritage	495	1978	
Not specified	7	32	

End points

End points reporting groups

Reporting group title	Nimenrix 3 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.

Reporting group title	Nimenrix 2 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	NeisVac-C Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	Nimenrix 3 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.

Reporting group title	Nimenrix 2 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	NeisVac-C Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Primary: Percentage of subjects with serum bactericidal assay using baby rabbit complement against meningococcal serogroups A, W-135 and Y (rSBA-MenA, rSBA-MenW-135 and rSBA-Y) antibody titers greater than or equal to (≥) the cut-off value.

End point title	Percentage of subjects with serum bactericidal assay using baby rabbit complement against meningococcal serogroups A, W-135 and Y (rSBA-MenA, rSBA-MenW-135 and rSBA-Y) antibody titers greater than or equal to (≥) the cut-off value.[1][2]

End point description:

The cut-off value for the rSBA-MenA, rSBA-MenW-135 and rSBA-Y titers was greater than or equal to (≥) 1:8.
Indication of the immunogenicity of the 2-dose and 3-dose schedules: the lower limit of the two-sided exact 95% CI for the percentage of subjects with post-primary vaccination rSBA antibody titre ≥ 1:8 is greater than or equal to the pre-defined clinical limit of 80%.

End point type	Primary

End point timeframe:

One month after the final primary vaccination at Month 3

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[2] - 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	Nimenrix 3 Group	Nimenrix 2 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	462	456		
Units: Percentage of Participants				
number (confidence interval 95%)				
rSBA-MenA	99.4 (98.1 to 99.9)	97.4 (95.4 to 98.6)		
rSBA-MenW-135	99.1 (97.8 to 99.8)	99.1 (97.8 to 99.8)		
rSBA-MenY	93.1 (90.3 to 95.2)	98.2 (96.6 to 99.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenC antibody titers ≥ the cut-off value

End point title	Number of subjects with rSBA-MenC antibody titers ≥ the cut-off value

End point description:

The cut-off value for rSBA-MenC titers was ≥ 1:8.

End point type	Primary

End point timeframe:

One month after the final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	461	456	455	457
Units: Participants	459	450	453	457

Statistical analyses

Statistical analysis title	Difference in % of subjects with rSBA-MenC ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix 3 Group compared to the Menjugate Group, two-sided standardized asymptotic 95% CI (confidence interval) for the groups difference [Nimenrix 3 Group minus Menjugate Group] in the percentages of subjects with bactericidal vaccine response to MenC was computed.

Comparison groups	Nimenrix 3 Group v Menjugate Group
Number of subjects included in analysis	916
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.17
upper limit	1.2

Statistical analysis title	Difference in % of subjects with rSBA-MenC ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix 3 Group compared to the NeisVac-C Group, two-sided standardized asymptotic 95% CI for the groups difference [Nimenrix 3 Group minus NeisVac-C Group] in the percentages of subjects with bactericidal vaccine response to MenC was computed.

Comparison groups	Nimenrix 3 Group v NeisVac-C Group
Number of subjects included in analysis	918
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percenttage
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.57
upper limit	0.4

Statistical analysis title	Difference in % of subjects with rSBA-MenC ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix 2 Group compared to Menjugate Group, two-sided standardized asymptotic 95% CI for the groups difference [Nimenrix 2 Group minus Menjugate Group] in the percentages of subjects with bactericidal vaccine response to MenC was computed.

Comparison groups	Nimenrix 2 Group v Menjugate Group
Number of subjects included in analysis	911
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	-0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.45
upper limit	0.43

Statistical analysis title	Difference in % of subjects with rSBA-MenC ≥1:8

Statistical analysis description:

To demonstrate the non-inferiority of the Nimenrix 2 Group compared to NeisVac-C Group, two-sided standardized asymptotic 95% CI for the groups difference [Nimenrix 2 Group minus NeisVac-C Group] in the percentages of subjects with bactericidal vaccine response to MenC was computed.

Comparison groups	Nimenrix 2 Group v NeisVac-C Group
Number of subjects included in analysis	913
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	-1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.84
upper limit	-0.48

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

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

End point description:

The cut-off values for rSBA-Men antibody titers were greater than or equal to (≥) 1:8 and ≥ 1:128 at pre-vaccination

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	220	207	220
Units: Participants				
rSBA-MenA ≥ 1:8	2	4	2	2
rSBA-MenA ≥ 1:128	1	0	0	0
rSBA-MenC ≥ 1:8	12	10	15	14
rSBA-MenC ≥ 1:128	2	1	6	5
rSBA-MenW-135 ≥ 1:8	8	12	5	3
rSBA-MenW-135 ≥ 1:128	0	1	1	1
rSBA-MenY ≥ 1:8	6	6	8	3
rSBA-MenY ≥ 1:128	0	3	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers at Month 0

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers at Month 0

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	223	220	207	220
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	4.1 (4 to 4.2)	4.1 (4 to 4.2)	4.1 (4 to 4.3)	4.1 (3.9 to 4.3)
rSBA-MenC	4.4 (4.1 to 4.8)	4.3 (4.1 to 4.5)	4.9 (4.4 to 5.5)	4.7 (4.3 to 5.2)
rSBA-MenW-135	4.3 (4.1 to 4.5)	4.4 (4.1 to 4.6)	4.3 (3.9 to 4.8)	4.3 (3.9 to 4.7)
rSBA-MenY	4.2 (4 to 4.4)	4.2 (4 to 4.5)	4.7 (4.2 to 5.2)	4.2 (3.9 to 4.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titers above the cut-off values

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

End point description:

The cut-off values for the rSBA-Men antibody titers were greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	441	463	446	461
Units: Participants				
rSBA-MenA ≥ 1:8, Month 10	300	279	26	23
rSBA-MenA ≥ 1:128, Month 10	107	99	11	3
rSBA-MenA ≥ 1:8, Month 11	437	460	21	19
rSBA-MenA ≥ 1:128, Month 11	433	456	8	12
rSBA-MenC ≥ 1:8, Month 10	324	348	229	356
rSBA-MenC ≥ 1:128, Month 10	108	183	79	195
rSBA-MenC ≥ 1:8, Month 11	437	462	439	459
rSBA-MenC ≥ 1:128, Month 11	432	454	426	457
rSBA-MenW-135 ≥ 1:8, Month 10	372	417	18	27
rSBA-MenW-135 ≥ 1:128, Month 10	221	254	16	22
rSBA-MenW-135 ≥ 1:8, Month 11	433	461	34	37
rSBA-MenW-135 ≥ 1:128, Month 11	430	457	31	31
rSBA-MenY ≥ 1:8, Month 10	364	383	54	47
rSBA-MenY ≥ 1:128, Month 10	126	168	41	37
rSBA-MenY ≥ 1:8, Month 11	436	459	45	40
rSBA-MenY ≥ 1:128, Month 11	419	445	37	34

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	441	463	446	461
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, Month 10	22.9 (19.8 to 26.5)	19.5 (16.8 to 22.6)	4.7 (4.3 to 5.0)	4.4 (4.2 to 4.6)
rSBA-MenA, Month 11	1417.6 (1281.4 to 1568.3)	1561.0 (1412.3 to 1725.3)	4.6 (4.3 to 4.9)	4.7 (4.3 to 5.0)
rSBA-MenC, Month 10	25.7 (22.3 to 29.6)	43.7 (37.4 to 51.1)	16.0 (13.8 to 18.5)	49.3 (42.1 to 57.7)
rSBA-MenC, Month 11	1154.6 (1034.1 to 1289.0)	1177.0 (1059.1 to 1308.0)	1051.4 (919.6 to 1202.1)	1960.2 (1776.4 to 2163.1)
rSBA-MenW-135, Month 10	68.7 (58.3 to 81.0)	97.7 (83.3 to 114.5)	4.7 (4.4 to 5.1)	5.0 (4.6 to 5.5)
rSBA-MenW-135, Month 11	1955.9 (1729.6 to 2211.9)	2777.2 (2485.1 to 3103.6)	5.5 (5.0 to 6.1)	5.6 (5.0 to 6.2)
rSBA-MenY, Month 10	35.4 (30.6 to 41.0)	47.0 (40.3 to 54.7)	6.5 (5.7 to 7.4)	6.0 (5.4 to 6.8)
rSBA-MenY, Month 11	630.6 (564.1 to 705.1)	881.3 (787.5 to 986.4)	6.1 (5.4 to 6.8)	5.8 (5.2 to 6.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay using human complement against meningococcal serogroups (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titers above the cut-off values

End point title	Number of subjects with serum bactericidal assay using human complement against meningococcal serogroups (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titers above the cut-off values

End point description:

The cut-off values for hSBA antibody titers were greater than or equal to (≥) 1:4 and ≥ 1:8.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	214	218	205	226
Units: Participants				
hSBA-MenA ≥ 1:4, Month 0	34	31	41	34
hSBA-MenA ≥ 1:8, Month 0	28	19	27	27
hSBA-MenA ≥ 1:4, Month 3	197	195	21	18
hSBA-MenA ≥ 1:8, Month 3	196	195	15	14
hSBA-MenC ≥ 1:4, Month 0	43	35	50	44
hSBA-MenC ≥ 1:8, Month 0	43	35	49	42
hSBA-MenC ≥ 1:4, Month 3	213	215	202	226
hSBA-MenC ≥ 1:8, Month 3	213	215	202	226
hSBA-MenW-135 ≥ 1:4, Month 0	50	46	54	37
hSBA-MenW-135 ≥ 1:8, Month 0	49	44	52	36
hSBA-MenW-135 ≥ 1:4, Month 3	197	217	6	3
hSBA-MenW-135 ≥ 1:8, Month 3	197	217	4	3
hSBA-MenY ≥ 1:4, Month 0	73	73	71	78
hSBA-MenY ≥ 1:8, Month 0	73	72	71	77
hSBA-MenY ≥ 1:4, Month 3	187	209	11	5
hSBA-MenY ≥ 1:8, Month 3	185	209	11	4

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers at Month 0 and Month 3

End point title	hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers at Month 0 and Month 3

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	214	218	205	226
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA, Month 0	2.8 (2.5 to 3.2)	2.7 (2.4 to 3)	3 (2.7 to 3.4)	2.9 (2.6 to 3.3)
hSBA-MenA, Month 3	240.9 (207.8 to 279.3)	157.2 (131.4 to 188.1)	2.5 (2.2 to 2.7)	2.3 (2.2 to 2.5)
hSBA-MenC, Month 0	3.9 (3.2 to 4.7)	3.6 (3 to 4.4)	4.9 (3.9 to 6.2)	3.9 (3.2 to 4.7)

hSBA-MenC, Month 3	765.6 (647.4 to 905.3)	1308.3 (1051.7 to 1627.4)	3188.1 (2645.8 to 3841.5)	2626.5 (2218.9 to 3109)
hSBA-MenW-135, Month 0	5 (3.9 to 6.3)	4.7 (3.8 to 6)	5 (4 to 6.3)	3.7 (3.1 to 4.6)
hSBA-MenW-135, Month 3	190.9 (160 to 227.8)	753.5 (643.8 to 881.8)	2.1 (2 to 2.3)	2.1 (2 to 2.3)
hSBA-MenY, Month 0	8 (6.1 to 10.5)	8 (6.1 to 10.5)	7.1 (5.5 to 9.2)	8.1 (6.3 to 10.4)
hSBA-MenY, Month 3	66.5 (53.7 to 82.2)	328.1 (275.8 to 390.2)	2.4 (2.1 to 2.7)	2.1 (2 to 2.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers above the cut-off values

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

End point description:

The cut-off values for hSBA antibody titers were greater than or equal to (≥) 1:4 and ≥ 1:8.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	221	219	219
Units: Participants				
hSBA-MenA ≥ 1:4, Month 10	142	119	28	26
hSBA-MenA ≥ 1:8, Month 10	141	119	26	26
hSBA-MenA ≥ 1:4, Month 11	210	213	50	55
hSBA-MenA ≥ 1:8, Month 11	210	213	50	55
hSBA-MenC ≥ 1:4, Month 10	184	198	160	196
hSBA-MenC ≥ 1:8, Month 10	184	198	160	196
hSBA-MenC ≥ 1:4, Month 11	212	220	216	219
hSBA-MenC ≥ 1:8, Month 11	212	220	216	219
hSBA-MenW-135 ≥ 1:4, Month 10	196	201	1	6
hSBA-MenW-135 ≥ 1:8, Month 10	196	201	1	6
hSBA-MenW-135 ≥ 1:4, Month 11	207	218	3	6
hSBA-MenW-135 ≥ 1:8, Month 11	207	218	3	6
hSBA-MenY ≥ 1:4, Month 10	185	204	6	10
hSBA-MenY ≥ 1:8, Month 10	185	204	6	10
hSBA-MenY ≥ 1:4, Month 11	206	217	7	12
hSBA-MenY ≥ 1:8, Month 11	206	217	7	12

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	221	219	219
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA, Month 10	32.0 (24.2 to 42.2)	14.5 (11.2 to 18.7)	2.7 (2.4 to 3.0)	2.7 (2.4 to 3.1)
hSBA-MenA, Month 11	1192.7 (978.4 to 1453.9)	1007.2 (835.7 to 1213.8)	3.9 (3.3 to 4.6)	4.2 (3.5 to 5.0)
hSBA-MenC, Month 10	116.1 (94.2 to 143.0)	181.4 (147.3 to 223.4)	76.8 (58.5 to 100.8)	213.7 (174.6 to 261.7)
hSBA-MenC, Month 11	4411.2 (3654.5 to 5324.6)	4992.3 (4085.7 to 6100.0)	5438.2 (4412.4 to 6702.3)	5542.3 (4765.2 to 6446.2)
hSBA-MenW-135, Month 10	248.1 (210.4 to 292.6)	332.4 (287.3 to 384.5)	2.0 (2.0 to 2.1)	2.3 (2.0 to 2.6)
hSBA-MenW-135, Month 11	3944.9 (3419.1 to 4551.7)	5122.7 (4504.2 to 5826.1)	2.1 (2.0 to 2.2)	2.3 (2.1 to 2.7)
hSBA-MenY, Month 10	99.8 (80.7 to 123.5)	140.2 (116.2 to 169.2)	2.2 (2.0 to 2.4)	2.4 (2.1 to 2.7)
hSBA-MenY, Month 11	2491.5 (2125.8 to 2920.1)	2954.0 (2497.9 to 3493.3)	2.3 (2.1 to 2.6)	2.4 (2.2 to 2.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes (anti-P) antibody concentrations above the cut-off values

End point title	Number of subjects with anti-pneumococcal serotypes (anti-P) antibody concentrations above the cut-off values

End point description:

The cut-off values for anti-1, anti-4, anti-5, anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19F and anti-23F concentrations were greater than or equal to (≥) 0.15 micrograms per milliliter (µg/mL) and ≥ 0.35 µg/mL

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	104	95	103
Units: Participants				
Anti-1 ≥ 0.15 µg/mL, Month 0	18	15	17	18
Anti-1 ≥ 0.35 µg/mL, Month 0	3	9	8	8
Anti-1 ≥ 0.15 µg/mL, Month 3	96	102	93	103
Anti-1 ≥ 0.35 µg/mL, Month 3	93	95	89	91
Anti-4 ≥ 0.15 µg/mL, Month 0	11	11	13	12
Anti-4 ≥ 0.35 µg/mL, Month 0	2	2	2	1
Anti-4 ≥ 0.15 µg/mL, Month 3	96	102	95	103
Anti-4 ≥ 0.35 µg/mL, Month 3	94	99	93	99
Anti-5 ≥ 0.15 µg/mL, Month 0	42	32	39	33
Anti-5 ≥ 0.35 µg/mL, Month 0	10	5	9	14
Anti-5 ≥ 0.15 µg/mL, Month 3	95	102	93	101
Anti-5 ≥ 0.35 µg/mL, Month 3	84	86	80	92
Anti-6B ≥ 0.15 µg/mL, Month 0	55	42	41	50
Anti-6B ≥ 0.35 µg/mL, Month 0	27	19	20	26
Anti-6B ≥ 0.15 µg/mL, Month 3	88	95	88	90
Anti-6B ≥ 0.35 µg/mL, Month 3	71	82	75	81
Anti-7F ≥ 0.15 µg/mL, Month 0	38	43	44	49
Anti-7F ≥ 0.35 µg/mL, Month 0	13	18	20	16
Anti-7F ≥ 0.15 µg/mL, Month 3	96	102	93	103
Anti-7F ≥ 0.35 µg/mL, Month 3	94	99	93	103
Anti-9V ≥ 0.15 µg/mL, Month 0	38	44	35	43
Anti-9V ≥ 0.35 µg/mL, Month 0	9	18	12	16
Anti-9V ≥ 0.15 µg/mL, Month 3	94	102	90	103
Anti-9V ≥ 0.35 µg/mL, Month 3	92	99	88	99
Anti-14 ≥ 0.15 µg/mL, Month 0	72	69	74	80
Anti-14 ≥ 0.35 µg/mL, Month 0	53	57	57	67
Anti-14 ≥ 0.15 µg/mL, Month 3	96	103	95	103
Anti-14 ≥ 0.35 µg/mL, Month 3	96	103	95	103
Anti-18C ≥ 0.15 µg/mL, Month 0	30	44	45	43
Anti-18C ≥ 0.35 µg/mL, Month 0	14	18	20	10
Anti-18C ≥ 0.15 µg/mL, Month 3	96	101	93	103
Anti-18C ≥ 0.35 µg/mL, Month 3	90	100	89	101
Anti-19F ≥ 0.15 µg/mL, Month 0	41	61	51	53

Anti-19F ≥ 0.35 µg/mL, Month 0	21	30	27	23
Anti-19F ≥ 0.15 µg/mL, Month 3	94	100	94	102
Anti-19F ≥ 0.35 µg/mL, Month 3	92	94	90	99
Anti-23F ≥ 0.15 µg/mL, Month 0	37	38	29	40
Anti-23F ≥ 0.35 µg/mL, Month 0	16	13	13	18
Anti-23F ≥ 0.15 µg/mL, Month 3	90	99	91	98
Anti-23F ≥ 0.35 µg/mL, Month 3	83	83	77	86

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes antibody concentrations at Month 0 and Month 3

End point title	Anti-pneumococcal serotypes antibody concentrations at Month 0 and Month 3

End point description:

Anti-1, anti-4, anti-5, anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19F and anti-23F antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in µg/mL.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	104	95	103
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1, Month 0	0.09 (0.08 to 0.10)	0.10 (0.09 to 0.12)	0.10 (0.09 to 0.12)	0.10 (0.09 to 0.11)
Anti-1, Month 3	1.36 (1.15 to 1.62)	1.13 (0.96 to 1.34)	1.26 (1.06 to 1.50)	1.02 (0.88 to 1.18)
Anti-4, Month 0	0.09 (0.08 to 0.09)	0.09 (0.08 to 0.09)	0.09 (0.08 to 0.10)	0.09 (0.08 to 0.09)
Anti-4, Month 3	1.84 (1.58 to 2.15)	1.56 (1.31 to 1.86)	1.77 (1.50 to 2.10)	1.60 (1.37 to 1.85)
Anti-5, Month 0	0.13 (0.11 to 0.15)	0.12 (0.10 to 0.13)	0.13 (0.11 to 0.15)	0.12 (0.11 to 0.15)
Anti-5, Month 3	0.82 (0.71 to 0.95)	0.70 (0.61 to 0.81)	0.77 (0.66 to 0.89)	0.74 (0.65 to 0.85)
Anti-6B, Month 0	0.18 (0.15 to 0.21)	0.15 (0.13 to 0.19)	0.15 (0.13 to 0.19)	0.18 (0.15 to 0.22)
Anti-6B, Month 3	0.79 (0.62 to 1.00)	0.90 (0.71 to 1.14)	1.08 (0.84 to 1.38)	0.86 (0.67 to 1.12)
Anti-7F, Month 0	0.13 (0.11 to 0.16)	0.17 (0.13 to 0.21)	0.16 (0.13 to 0.20)	0.15 (0.13 to 0.18)
Anti-7F, Month 3	1.91 (1.63 to 2.23)	1.84 (1.56 to 2.18)	2.13 (1.82 to 2.49)	1.87 (1.62 to 2.15)

Anti-9V, Month 0	0.13 (0.11 to 0.15)	0.15 (0.13 to 0.18)	0.13 (0.11 to 0.15)	0.14 (0.12 to 0.17)
Anti-9V, Month 3	1.31 (1.10 to 1.56)	1.12 (0.97 to 1.29)	1.22 (1.02 to 1.46)	1.21 (1.07 to 1.38)
Anti-14, Month 0	0.50 (0.37 to 0.67)	0.61 (0.44 to 0.85)	0.59 (0.44 to 0.79)	0.74 (0.56 to 0.99)
Anti-14, Month 3	7.55 (6.40 to 8.90)	7.40 (6.35 to 8.62)	8.51 (7.09 to 10.22)	6.04 (5.04 to 7.24)
Anti-18C, Month 0	0.13 (0.11 to 0.16)	0.16 (0.13 to 0.20)	0.17 (0.14 to 0.21)	0.14 (0.12 to 0.16)
Anti-18C, Month 3	2.14 (1.74 to 2.64)	1.77 (1.47 to 2.13)	2.39 (1.96 to 2.93)	2.80 (2.40 to 3.27)
Anti-19F, Month 0	0.15 (0.13 to 0.19)	0.23 (0.19 to 0.28)	0.20 (0.16 to 0.25)	0.19 (0.15 to 0.23)
Anti-19F, Month 3	3.01 (2.37 to 3.82)	2.60 (2.01 to 3.35)	2.89 (2.26 to 3.69)	2.85 (2.29 to 3.54)
Anti-23F, Month 0	0.14 (0.11 to 0.16)	0.14 (0.11 to 0.17)	0.13 (0.11 to 0.15)	0.15 (0.12 to 0.17)
Anti-23F, Month 3	0.96 (0.78 to 1.18)	0.85 (0.69 to 1.06)	1.08 (0.86 to 1.36)	0.94 (0.77 to 1.16)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes antibody concentrations above the cut-off values

End point title	Number of subjects with anti-pneumococcal serotypes antibody concentrations above the cut-off values

End point description:

The cut-off values for anti-1, anti-4, anti-5, anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19F and anti-23F concentrations were ≥ 0.15 µg/mL and ≥ 0.35 µg/mL

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	107	106	110
Units: Participants				
Anti-1 ≥ 0.15 µg/mL, Month 10	65	64	72	57
Anti-1 ≥ 0.35 µg/mL, Month 10	21	20	24	10
Anti-1 ≥ 0.15 µg/mL, Month 11	104	106	99	103
Anti-1 ≥ 0.35 µg/mL, Month 11	102	104	97	101
Anti-4 ≥ 0.15 µg/mL, Month 10	83	87	91	94
Anti-4 ≥ 0.35 µg/mL, Month 10	38	35	48	30
Anti-4 ≥ 0.15 µg/mL, Month 11	104	107	100	104
Anti-4 ≥ 0.35 µg/mL, Month 11	104	107	99	104
Anti-5 ≥ 0.15 µg/mL, Month 10	90	91	94	93
Anti-5 ≥ 0.35 µg/mL, Month 10	44	43	48	43

Anti-5 ≥ 0.15 µg/mL, Month 11	101	104	98	101
Anti-5 ≥ 0.35 µg/mL, Month 11	92	96	95	96
Anti-6B ≥ 0.15 µg/mL, Month 10	96	104	104	103
Anti-6B ≥ 0.35 µg/mL, Month 10	71	84	83	83
Anti-6B ≥ 0.15 µg/mL, Month 11	103	106	100	104
Anti-6B ≥ 0.35 µg/mL, Month 11	103	105	100	104
Anti-7F ≥ 0.15 µg/mL, Month 10	98	103	106	104
Anti-7F ≥ 0.35 µg/mL, Month 10	76	78	75	78
Anti-7F ≥ 0.15 µg/mL, Month 11	104	107	100	104
Anti-7F ≥ 0.35 µg/mL, Month 11	104	107	100	104
Anti-9V ≥ 0.15 µg/mL, Month 10	81	82	88	89
Anti-9V ≥ 0.35 µg/mL, Month 10	42	30	43	33
Anti-9V ≥ 0.15 µg/mL, Month 11	104	107	100	104
Anti-9V ≥ 0.35 µg/mL, Month 11	102	105	99	102
Anti-14 ≥ 0.15 µg/mL, Month 10	102	106	106	106
Anti-14 ≥ 0.35 µg/mL, Month 10	100	103	99	103
Anti-14 ≥ 0.15 µg/mL, Month 11	104	107	100	104
Anti-14 ≥ 0.35 µg/mL, Month 11	104	107	100	104
Anti-18C ≥ 0.15 µg/mL, Month 10	82	89	97	101
Anti-18C ≥ 0.35 µg/mL, Month 10	45	50	54	58
Anti-18C ≥ 0.15 µg/mL, Month 11	103	107	100	104
Anti-18C ≥ 0.35 µg/mL, Month 11	103	106	100	104
Anti-19F ≥ 0.15 µg/mL, Month 10	102	107	106	107
Anti-19F ≥ 0.35 µg/mL, Month 10	96	98	103	102
Anti-19F ≥ 0.15 µg/mL, Month 11	104	107	100	104
Anti-19F ≥ 0.35 µg/mL, Month 11	104	107	100	104
Anti-23F ≥ 0.15 µg/mL, Month 10	94	103	102	101
Anti-23F ≥ 0.35 µg/mL, Month 10	58	61	63	63
Anti-23F ≥ 0.15 µg/mL, Month 11	101	106	98	104
Anti-23F ≥ 0.35 µg/mL, Month 11	101	106	98	104

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes antibody concentrations

End point title	Anti-pneumococcal serotypes antibody concentrations

End point description:

Anti-1, anti-4, anti-5, anti-6B, anti-7F, anti-9V, anti-14, anti-18C, anti-19F and anti-23F antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in µg/mL.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	104	107	106	110
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1, Month 10	0.19 (0.16 to 0.22)	0.17 (0.15 to 0.20)	0.20 (0.17 to 0.23)	0.15 (0.13 to 0.17)
Anti-1, Month 11	2.03 (1.72 to 2.41)	1.67 (1.39 to 2.01)	2.18 (1.81 to 2.64)	1.72 (1.46 to 2.03)
Anti-4, Month 10	0.27 (0.23 to 0.32)	0.27 (0.23 to 0.32)	0.31 (0.27 to 0.37)	0.25 (0.22 to 0.28)
Anti-4, Month 11	2.42 (2.11 to 2.78)	2.16 (1.86 to 2.51)	2.86 (2.46 to 3.34)	2.12 (1.87 to 2.40)
Anti-5, Month 10	0.32 (0.27 to 0.37)	0.28 (0.24 to 0.32)	0.30 (0.26 to 0.35)	0.27 (0.23 to 0.30)
Anti-5, Month 11	0.89 (0.78 to 1.02)	0.87 (0.76 to 1.00)	0.95 (0.83 to 1.09)	0.84 (0.74 to 0.97)
Anti-6B, Month 10	0.62 (0.52 to 0.73)	0.64 (0.54 to 0.76)	0.68 (0.58 to 0.80)	0.59 (0.51 to 0.69)
Anti-6B, Month 11	2.91 (2.49 to 3.41)	3.02 (2.57 to 3.56)	3.70 (3.18 to 4.29)	3.20 (2.79 to 3.68)
Anti-7F, Month 10	0.50 (0.44 to 0.57)	0.52 (0.45 to 0.61)	0.57 (0.50 to 0.66)	0.46 (0.40 to 0.52)
Anti-7F, Month 11	2.89 (2.53 to 3.30)	2.88 (2.51 to 3.31)	3.38 (2.94 to 3.89)	2.78 (2.43 to 3.17)
Anti-9V, Month 10	0.27 (0.23 to 0.33)	0.23 (0.20 to 0.27)	0.28 (0.24 to 0.32)	0.25 (0.22 to 0.28)
Anti-9V, Month 11	1.49 (1.30 to 1.70)	1.31 (1.15 to 1.49)	1.47 (1.27 to 1.71)	1.33 (1.18 to 1.49)
Anti-14, Month 10	1.69 (1.39 to 2.05)	1.64 (1.37 to 1.97)	1.74 (1.46 to 2.09)	1.42 (1.18 to 1.70)
Anti-14, Month 11	8.51 (7.20 to 10.07)	7.63 (6.62 to 8.79)	9.75 (8.36 to 11.38)	7.94 (6.85 to 9.20)
Anti-18C, Month 10	0.33 (0.27 to 0.40)	0.33 (0.28 to 0.39)	0.39 (0.33 to 0.46)	0.38 (0.33 to 0.44)
Anti-18C, Month 11	2.30 (2.00 to 2.64)	2.10 (1.84 to 2.39)	3.08 (2.65 to 3.58)	2.78 (2.44 to 3.17)
Anti-19F, Month 10	1.22 (1.04 to 1.45)	1.26 (1.05 to 1.52)	1.34 (1.13 to 1.59)	1.10 (0.94 to 1.29)
Anti-19F, Month 11	9.55 (8.23 to 11.09)	8.06 (6.88 to 9.46)	9.74 (8.20 to 11.58)	8.43 (7.35 to 9.66)
Anti-23F, Month 10	0.39 (0.34 to 0.46)	0.45 (0.39 to 0.53)	0.47 (0.40 to 0.56)	0.41 (0.35 to 0.48)
Anti-23F, Month 11	3.74 (3.23 to 4.34)	3.73 (3.19 to 4.35)	4.24 (3.60 to 5.00)	3.73 (3.30 to 4.21)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) concentrations ≥ the cut-off value

End point title	Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-D and anti-T concentrations was greater than or equal to (≥) 0.1 IU/mL

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	113	123	115
Units: Participants				
Anti-D, Month 0	37	43	56	39
Anti-D, Month 3	117	113	123	115
Anti-T, Month 0	104	91	107	91
Anti-T, Month 3	117	113	123	114

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D and anti-T antibody concentrations at Month 0 and Month 3

End point title	Anti-D and anti-T antibody concentrations at Month 0 and Month 3

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	113	123	115
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, Month 0	0.092 (0.077 to 0.11)	0.098 (0.082 to 0.117)	0.133 (0.108 to 0.165)	0.093 (0.078 to 0.112)
Anti-D, Month 3	2.171 (1.893 to 2.49)	2.64 (2.274 to 3.065)	3.005 (2.657 to 3.4)	2.488 (2.169 to 2.855)
Anti-T, Month 0	0.484 (0.393 to 0.596)	0.496 (0.388 to 0.636)	0.727 (0.581 to 0.909)	0.5 (0.387 to 0.647)
Anti-T, Month 3	3.137 (2.79 to 3.527)	3.37 (2.98 to 3.811)	2.847 (2.523 to 3.212)	4.339 (3.833 to 4.912)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-D and anti-T antibody concentrations ≥ the cut-off value

End point title	Number of subjects with anti-D and anti-T antibody concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-D and anti-T concentrations was greater than or equal to (≥) 0.1 IU/mL

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: Participants				
Anti-D, Month 10	98	98	116	113
Anti-D, Month 11	116	111	118	118
Anti-T, Month 10	114	111	118	117
Anti-T, Month 11	116	111	118	118

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D and anti-T antibody concentrations

End point title	Anti-D and anti-T antibody concentrations

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, Month 10	0.292 (0.246 to 0.348)	0.325 (0.272 to 0.389)	0.507 (0.433 to 0.594)	0.379 (0.327 to 0.440)
Anti-D, Month 11	5.032 (4.337 to 5.838)	5.438 (4.600 to 6.430)	9.078 (7.959 to 10.354)	6.437 (5.589 to 7.413)
Anti-T, Month 10	0.832 (0.739 to 0.937)	0.780 (0.677 to 0.898)	0.684 (0.590 to 0.793)	0.956 (0.835 to 1.094)
Anti-T, Month 11	10.234 (9.128 to 11.475)	11.004 (9.721 to 12.456)	8.400 (7.285 to 9.685)	13.016 (11.640 to 14.554)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) concentrations ≥ the cut-off value

End point title	Number of subjects with anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-PT, anti-FHA and anti-PRN concentrations was greater than or equal to (≥) 5 enzyme-linked immunosorbent assay (ELISA) units per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	112	123	115
Units: Participants				
Anti-PT, Month 0	23	32	28	31
Anti-PT, Month 3	117	111	122	115
Anti-FHA, Month 0	83	85	93	78
Anti-FHA, Month 3	117	111	123	115
Anti-PRN, Month 0	31	39	44	32
Anti-PRN, Month 3	117	112	122	115

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PT, anti-FHA and anti-PRN antibody concentrations at Month 0 and Month 3

End point title	Anti-PT, anti-FHA and anti-PRN antibody concentrations at Month 0 and Month 3

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in EL.U/mL.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	112	123	115
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, Month 0	3.4 (3 to 3.8)	3.9 (3.3 to 4.5)	3.6 (3.2 to 4.2)	4.1 (3.5 to 4.9)
Anti-PT, Month 3	52.7 (46.5 to 59.8)	56.3 (49.5 to 64)	56.5 (50.5 to 63.1)	56.4 (50.6 to 63)
Anti-FHA, Month 0	9.7 (8 to 11.9)	13.2 (10.7 to 16.4)	11.4 (9.4 to 13.9)	11.9 (9.4 to 15.1)
Anti-FHA, Month 3	124.3 (109 to 141.8)	149.2 (131.2 to 169.6)	139.1 (123.2 to 157.1)	132 (115.1 to 151.3)
Anti-PRN, Month 0	4 (3.4 to 4.7)	5 (4 to 6.2)	4.6 (3.9 to 5.4)	4.7 (3.8 to 5.9)
Anti-PRN, Month 3	122 (104.1 to 143.1)	134.9 (119 to 152.9)	118.2 (101.5 to 137.7)	132 (113.6 to 153.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PT, anti-FHA and anti-PRN concentrations ≥ the cut-off value

End point title	Number of subjects with anti-PT, anti-FHA and anti-PRN concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-PT, anti-FHA and anti-PRN concentrations was greater than or equal to (≥) 5 EL.U/mL.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: Participants				
Anti-PT, Month 10	100	94	104	102
Anti-PT, Month 11	110	109	116	116
Anti-FHA, Month 10	112	106	118	115
Anti-FHA, Month 11	113	111	116	116
Anti-PRN, Month 10	105	98	109	105
Anti-PRN, Month 11	116	110	118	118

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PT, anti-FHA and anti-PRN antibody concentrations

End point title	Anti-PT, anti-FHA and anti-PRN antibody concentrations

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in EL.U/mL.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, Month 10	11.0 (9.4 to 12.9)	11.1 (9.4 to 13.1)	13.1 (11.1 to 15.4)	11.4 (9.9 to 13.3)
Anti-PT, Month 11	82.5 (71.9 to 94.7)	78.2 (67.8 to 90.2)	84.7 (73.5 to 97.5)	82.7 (72.5 to 94.4)
Anti-FHA, Month 10	34.5 (29.6 to 40.2)	33.1 (27.5 to 39.8)	37.4 (32.1 to 43.5)	34.9 (29.8 to 40.9)
Anti-FHA, Month 11	285.5 (250.6 to 325.4)	296.3 (258.5 to 339.7)	305.9 (269.0 to 347.8)	302.9 (266.8 to 343.9)
Anti-PRN, Month 10	17.9 (14.8 to 21.6)	15.7 (13.1 to 18.8)	19.9 (16.5 to 23.9)	17.9 (14.8 to 21.6)
Anti-PRN, Month 11	283.7 (233.9 to 344.1)	290.8 (242.5 to 348.7)	291.7 (246.1 to 345.7)	334.3 (282.9 to 395.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-hepatitis B surface antigen (anti-HBs) antibody concentrations above the cut-off values

End point title	Number of subjects with anti-hepatitis B surface antigen (anti-HBs) antibody concentrations above the cut-off values

End point description:

The cut-off values for anti-HBs concentrations were greater than or equal to (≥) 10 milli-international units per milliliter (mIU/mL) and ≥ 100 mIU/mL.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	84	97	93
Units: Participants				
Anti-HBs ≥ 10 mIU/mL, Month 0	33	34	39	28
Anti-HBs ≥ 10 mIU/mL, Month 3	85	84	94	79
Anti-HBs ≥ 100 mIU/mL, Month 0	17	14	14	8
Anti-HBs ≥ 100 mIU/mL, Month 3	74	79	89	73

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations at Month 0 and Month 3

End point title	Anti-HBs antibody concentrations at Month 0 and Month 3

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in milli-international units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	84	97	93
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Month 0	12.0 (7.6 to 18.7)	13.7 (8.4 to 22.4)	11.3 (7.7 to 16.7)	7.5 (5.4 to 10.5)

Anti-HBs, Month 3	692.3 (513.2 to 934.0)	732.2 (555.1 to 965.8)	848.3 (663.7 to 1084.1)	729.5 (530.3 to 1003.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-HBs antibody concentrations above the cut-off values

End point title	Number of subjects with anti-HBs antibody concentrations above the cut-off values

End point description:

The cut-off values for anti-HBs concentrations were greater than or equal to (≥) 10 mIU/mL and ≥ 100 mIU/mL.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	103	100
Units: Participants				
Anti-HBs ≥ 10 mIU/mL, Month 10	91	86	96	94
Anti-HBs ≥ 10 mIU/mL, Month 11	95	97	103	100
Anti-HBs ≥ 100 mIU/mL, Month 10	67	58	75	65
Anti-HBs ≥ 100 mIU/mL, Month 11	93	97	102	97

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HBs antibody concentrations

End point title	Anti-HBs antibody concentrations

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in milli-international units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	97	103	100
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, Month 10	150.5 (111.4 to 203.3)	138.2 (99.3 to 192.3)	196.6 (141.6 to 273.1)	141.9 (106.5 to 189.0)
Anti-HBs, Month 11	3624.9 (2570.0 to 5112.8)	4129.8 (3095.4 to 5509.8)	4866.4 (3723.5 to 6360.1)	3878.7 (2861.7 to 5257.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polyribosyl ribitol phosphate (anti-PRP) concentrations ≥ the cut-off values

End point title	Number of subjects with anti-polyribosyl ribitol phosphate (anti-PRP) concentrations ≥ the cut-off values

End point description:

The cut-off values for anti-PRP antibody concentrations were greater than or equal to (≥) 0.15 micrograms per milliliter (µg/mL) and ≥ 1.0 µg/mL.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119	113	123	114
Units: Participants				
Anti-PRP ≥ 0.15 µg/mL, Month 0	46	55	46	47
Anti-PRP ≥ 0.15 µg/mL, Month 3	119	113	121	113
Anti-PRP ≥ 1.0 µg/mL, Month 0	9	19	10	7
Anti-PRP ≥ 1.0 µg/mL, Month 3	106	101	94	106

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations at Month 0 and Month 3

End point title	Anti-PRP antibody concentrations at Month 0 and Month 3

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	119	113	123	114
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, Month 0	0.158 (0.131 to 0.191)	0.213 (0.168 to 0.27)	0.162 (0.132 to 0.198)	0.162 (0.133 to 0.196)
Anti-PRP, Month 3	4.011 (3.275 to 4.912)	3.573 (2.946 to 4.334)	2.752 (2.144 to 3.534)	4.662 (3.788 to 5.739)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PRP antibody concentrations above the cut-off values

End point title	Number of subjects with anti-PRP antibody concentrations above the cut-off values

End point description:

The cut-off values for anti-PRP antibody concentrations were greater than or equal to (≥) 0.15 µg/mL and ≥ 1.0 µg/mL.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: Participants				
Anti-PRP ≥ 0.15 µg/mL, Month 10	92	91	91	100
Anti-PRP ≥ 0.15 µg/mL, Month 11	116	112	119	118
Anti-PRP ≥ 1.0 µg/mL, Month 10	23	20	40	31
Anti-PRP ≥ 1.0 µg/mL, Month 11	113	112	119	114

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

End point title	Anti-PRP antibody concentrations

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	116	112	119	118
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, Month 10	0.378 (0.308 to 0.464)	0.400 (0.324 to 0.494)	0.535 (0.404 to 0.707)	0.535 (0.427 to 0.671)
Anti-PRP, Month 11	17.350 (14.124 to 21.313)	17.519 (14.041 to 21.859)	22.879 (18.147 to 28.847)	23.973 (19.194 to 29.941)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-poliovirus type 1, 2 and 3 antibody concentrations ≥ the cut-off value

End point title	Number of subjects with anti-poliovirus type 1, 2 and 3 antibody concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-poliovirus type 1, 2 and 3 antibody concentrations was greater than or equal to (≥) 1:8.

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	83	90	86
Units: Participants				
Anti-Polio 1, Month 0	52	46	54	46
Anti-Polio 1, Month 3	91	83	89	84

Anti-Polio 2, Month 0	39	40	44	41
Anti-Polio 2, Month 3	81	70	81	70
Anti-Polio 3, Month 0	21	21	11	23
Anti-Polio 3, Month 3	93	79	87	77

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 antibody titers at Month 0 and Month 3

End point title	Anti-polio type 1, 2 and 3 antibody titers at Month 0 and Month 3

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-primary vaccination at Month 0 and one month after final primary vaccination at Month 3

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	83	90	86
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, Month 0	32.7 (22.5 to 47.5)	40.2 (27.3 to 59.3)	28.1 (20.1 to 39.3)	30.7 (21.5 to 43.9)
Anti-Polio 1, Month 3	279.6 (222.4 to 351.5)	317.9 (227.6 to 444)	424.1 (323.1 to 556.6)	277.7 (200.7 to 384.1)
Anti-Polio 2, Month 0	19.4 (13.2 to 28.7)	28 (18.4 to 42.5)	17.4 (12.7 to 23.8)	22.9 (15.6 to 33.5)
Anti-Polio 2, Month 3	225.2 (173.2 to 292.6)	244.8 (173.3 to 345.9)	274.5 (202.1 to 372.8)	232.7 (160.8 to 336.6)
Anti-Polio 3, Month 0	11.5 (7.6 to 17.5)	11.7 (7.8 to 17.5)	5.9 (4.7 to 7.5)	14.2 (8.8 to 22.8)
Anti-Polio 3, Month 3	642.7 (478.7 to 862.8)	675 (486.3 to 936.9)	674 (525.5 to 864.5)	494.3 (347.4 to 703.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polio type 1, 2 and 3 antibody concentrations ≥ the cut-off value

End point title	Number of subjects with anti-polio type 1, 2 and 3 antibody concentrations ≥ the cut-off value

End point description:

The cut-off value for anti-poliovirus type 1, 2 and 3 antibody concentrations was greater than or equal to (≥) 1:8.

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	85	85	86	87
Units: Participants				
Anti-Polio 1, Month 10	74	63	80	81
Anti-Polio 1, Month 11	85	85	81	84
Anti-Polio 2, Month 10	69	66	83	72
Anti-Polio 2, Month 11	70	74	71	68
Anti-Polio 3, Month 10	57	62	62	64
Anti-Polio 3, Month 11	79	67	74	69

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 antibody titers

End point title	Anti-polio type 1, 2 and 3 antibody titers

End point description:

Antibody titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Pre-Booster dose at Month 10 and one month post-Booster dose at Month 11

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	85	85	86	87
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-polio 1, Month 10	74.9 (56.3 to 99.6)	84.7 (60.0 to 119.7)	120.8 (92.5 to 157.8)	90.0 (65.8 to 123.0)
Anti-polio 1, Month 11	909.8 (694.1 to 1192.6)	1070.9 (812.5 to 1411.4)	1524.5 (1214.9 to 1913.0)	1217.7 (956.5 to 1550.2)
Anti-polio 2, Month 10	93.7 (71.1 to 123.5)	80.1 (57.6 to 111.5)	112.5 (86.7 to 146.1)	78.1 (57.6 to 105.9)

Anti-polio 2, Month 11	1205.7 (902.2 to 1611.3)	1306.3 (985.1 to 1732.2)	2068.0 (1602.7 to 2668.5)	1419.0 (1088.4 to 1849.9)
Anti-polio 3, Month 10	115.0 (80.1 to 165.2)	104.6 (77.9 to 140.3)	155.2 (118.3 to 203.7)	108.6 (77.6 to 152.1)
Anti-polio 3, Month 11	1681.0 (1285.1 to 2198.9)	2167.8 (1645.7 to 2855.6)	2136.2 (1688.1 to 2703.4)	1852.2 (1425.6 to 2406.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms

End point title	Number of subjects with any and grade 3 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 = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site. For the Nimenrix 2, Menjugate and NeisVac-C groups, results corresponding to Dose 2 are for Infanrix hexa and Synflorix vaccination at Visit 2 (Month 1), while results corresponding to Dose 3 refer to the vaccination at Visit 3 (Month 2).

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period following each dose and across doses from Day 0 to Month 3 (Primary Vaccination)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	518	523	509	518
Units: Participants				
Any Pain, Dose 1	247	243	243	233
Grade 3 Pain, Dose 1	32	33	28	34
Any Redness, Dose 1	241	229	236	230
Grade 3 Redness, Dose 1	9	5	9	5
Any Swelling, Dose 1	188	182	179	188
Grade 3 Swelling, Dose 1	6	4	14	6
Any Pain, Dose 2	212	210	230	214
Grade 3 Pain, Dose 2	23	37	23	29
Any Redness, Dose 2	261	271	283	284
Grade 3 Redness, Dose 2	3	5	10	2
Any Swelling, Dose 2	211	206	225	210
Grade 3 Swelling, Dose 2	3	6	14	10
Any Pain, Dose 3	168	180	180	193
Grade 3 Pain, Dose 3	13	18	15	22
Any Redness, Dose 3	247	265	308	274
Grade 3 Redness, Dose 3	9	6	13	9
Any Swelling, Dose 3	210	216	252	218

Grade 3 Swelling, Dose 3	8	6	11	13
Any Pain, Across doses	319	332	344	327
Grade 3 Pain, Across doses	54	67	48	69
Any Redness, Across doses	363	369	391	371
Grade 3 Redness, Across doses	18	15	24	15
Any Swelling, Across doses	326	318	343	317
Grade 3 Swelling, Across doses	15	11	27	24

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-meningococcal vaccination from Day 0 to Month 3

End point title	Number of subjects with any and grade 3 solicited local symptoms post-meningococcal vaccination from Day 0 to Month 3

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-meningococcal vaccination period following each dose and across doses from Day 0 to Month 3 (Primary Vaccination)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	518	523	509	518
Units: Participants				
Any Pain, Dose 1	161	155	158	157
Grade 3 Pain, Dose 1	18	17	12	24
Any Redness, Dose 1	132	128	138	140
Grade 3 Redness, Dose 1	2	1	2	1
Any Swelling, Dose 1	68	62	87	82
Grade 3 Swelling, Dose 1	1	0	3	0
Any Pain, Dose 2	125	0	0	0
Grade 3 Pain, Dose 2	9	0	0	0
Any Redness, Dose 2	131	0	0	0
Grade 3 Redness, Dose 2	0	0	0	0
Any Swelling, Dose 2	77	0	0	0
Grade 3 Swelling, Dose 2	0	0	0	0
Any Pain, Dose 3	106	124	130	142
Grade 3 Pain, Dose 3	7	11	9	12
Any Redness, Dose 3	162	169	214	197
Grade 3 Redness, Dose 3	0	0	0	1
Any Swelling, Dose 3	104	115	137	130

Grade 3 Swelling, Dose 3	0	1	0	4
Any Pain, Across doses	229	202	213	212
Grade 3 Pain, Across doses	29	26	19	33
Any Redness, Across doses	233	206	255	233
Grade 3 Redness, Across doses	2	1	2	2
Any Swelling, Across doses	154	136	175	164
Grade 3 Swelling, Across doses	1	1	3	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-Infanrix™ hexa vaccination from Day 0 to Month 3

End point title	Number of subjects with any and grade 3 solicited local symptoms post-Infanrix™ hexa vaccination from Day 0 to Month 3

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-Infanrix hexa vaccination period following each dose and across doses from Day 0 to Month 3 (Primary Vaccination)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	518	523	509	518
Units: Participants				
Any Pain, Dose 1	212	202	208	210
Grade 3 Pain, Dose 1	28	28	25	32
Any Redness, Dose 1	201	190	191	192
Grade 3 Redness, Dose 1	7	3	6	2
Any Swelling, Dose 1	148	148	128	147
Grade 3 Swelling, Dose 1	6	4	13	4
Any Pain, Dose 2	184	200	219	198
Grade 3 Pain, Dose 2	18	34	22	27
Any Redness, Dose 2	232	250	264	265
Grade 3 Redness, Dose 2	1	5	10	2
Any Swelling, Dose 2	182	185	208	195
Grade 3 Swelling, Dose 2	1	3	13	10
Any Pain, Dose 3	144	159	153	175
Grade 3 Pain, Dose 3	9	14	11	19
Any Redness, Dose 3	228	243	272	247
Grade 3 Redness, Dose 3	5	4	11	7
Any Swelling, Dose 3	191	200	227	197

Grade 3 Swelling, Dose 3	6	4	11	11
Any Pain, Across doses	289	311	314	310
Grade 3 Pain, Across doses	44	58	43	63
Any Redness, Across doses	336	344	358	349
Grade 3 Redness, Across doses	13	11	19	10
Any Swelling, Across doses	297	292	308	294
Grade 3 Swelling, Across doses	12	7	25	21

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-Synflorix vaccination

End point title	Number of subjects with any and grade 3 solicited local symptoms post-Synflorix vaccination

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-Synflorix vaccination period following each dose and across doses from Day 0 to Month 3 (Primary Vaccination)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	518	523	509	518
Units: Participants				
Any Pain, Dose 1	218	201	217	195
Grade 3 Pain, Dose 1	29	26	26	32
Any Redness, Dose 1	209	184	196	183
Grade 3 Redness, Dose 1	4	2	5	4
Any Swelling, Dose 1	135	136	130	120
Grade 3 Swelling, Dose 1	4	1	10	4
Any Pain, Dose 2	179	186	203	189
Grade 3 Pain, Dose 2	20	31	19	25
Any Redness, Dose 2	197	216	225	235
Grade 3 Redness, Dose 2	2	1	5	1
Any Swelling, Dose 2	154	162	156	155
Grade 3 Swelling, Dose 2	3	4	8	5
Any Pain, Dose 3	129	152	132	150
Grade 3 Pain, Dose 3	10	13	10	18
Any Redness, Dose 3	173	213	227	209
Grade 3 Redness, Dose 3	4	4	6	2
Any Swelling, Dose 3	136	152	164	146
Grade 3 Swelling, Dose 3	3	4	6	5

Any Pain, Across doses	285	304	312	291
Grade 3 Pain, Across doses	46	54	41	61
Any Redness, Across doses	297	322	331	316
Grade 3 Redness, Across doses	8	7	12	7
Any Swelling, Across doses	247	259	262	237
Grade 3 Swelling, Across doses	9	7	16	13

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-meningococcal vaccination

End point title	Number of subjects with any and grade 3 solicited local symptoms post-meningococcal vaccination

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-meningococcal booster vaccination period

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	491	510	496	503
Units: Participants				
Any Pain	191	203	203	181
Grade 3 Pain	24	23	31	18
Any Redness	186	221	213	228
Grade 3 Redness	3	6	5	4
Any Swelling	133	152	158	165
Grade 3 Swelling	1	2	2	5

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-Infanrix™ hexa vaccination

End point title	Number of subjects with any and grade 3 solicited local symptoms post-Infanrix™ hexa vaccination

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade

3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-Infanrix™ hexa booster vaccination period

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	491	510	495	504
Units: Participants				
Any Pain	240	241	242	221
Grade Pain	35	33	39	23
Any Redness	259	286	282	280
Grade 3 Redness	29	24	32	22
Any Swelling	212	226	244	240
Grade 3 Swelling	20	18	17	14

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited adverse events (AEs) from Day 0 to Month 3

End point title	Number of subjects with any unsolicited adverse events (AEs) from Day 0 to Month 3

End point description:

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

End point type	Secondary

End point timeframe:

Within 31-days (Days 0-30) post-each primary vaccination dose

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	528	524	516	527
Units: Participants	293	273	291	280

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms post-Synflorix™ vaccination

End point title	Number of subjects with any and grade 3 solicited local symptoms post-Synflorix™ vaccination

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = cried when limb was moved/spontaneously painful. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-Synflorix™ booster vaccination period

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	491	510	495	504
Units: Participants				
Any Pain	212	215	227	205
Grade 3 Pain	36	33	33	26
Any Redness	219	243	242	250
Grade 3 Redness	14	9	20	9
Any Swelling	173	174	189	193
Grade 3 Swelling	5	5	4	10

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms from Day 0 to Month 3

End point title	Number of subjects with any, grade 3 and related solicited general symptoms from Day 0 to Month 3

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and temperature [defined as rectal temperature greater than or equal to (≥) 38 degrees Celsius (°C)]. Any = occurrence of any general symptoms, regardless of their intensity grade or relationship to study vaccination. Grade 3 Drowsiness = Drowsiness that prevented normal activity. Grade 3 Irritability = Crying that could not be comforted/prevented normal activity. Grade 3 Loss of appetite = Not eating at all. Grade 3 Temperature= temperature above 40.0 (°C). Related = symptom assessed by the investigator as related to the vaccination. For the Nimenrix 2, Menjugate and NeisVac-C groups, results corresponding to Dose 2 are for Infanrix™ hexa and Synflorix™ vaccination at Visit 2 (Month 1), while results corresponding to Dose 3 refer to the vaccination at Visit 3 (Month 2).

End point type	Secondary

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period following each dose and across doses from Day 0 to Month 3 (Primary Vaccination)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	518	523	509	518
Units: Participants				
Any Drowsiness, Dose 1	298	282	285	297
Grade 3 Drowsiness, Dose 1	22	22	17	34
Related Drowsiness, Dose 1	163	167	163	178
Any Irritability, Dose 1	329	337	355	364
Grade 3 Irritability, Dose 1	54	41	45	54
Related Irritability, Dose 1	199	206	213	235
Any Loss of appetite, Dose 1	188	208	196	219
Grade 3 Loss of appetite, Dose 1	12	11	9	8
Related Loss of appetite, Dose 1	95	106	111	117
Any Temperature, Dose 1	166	162	170	183
Grade 3 Temperature, Dose 1	0	0	0	0
Related Temperature, Dose 1	128	119	122	144
Any Drowsiness, Dose 2	232	210	231	211
Grade 3 Drowsiness, Dose 2	20	20	17	12
Related Drowsiness, Dose 2	133	123	137	132
Any Irritability, Dose 2	328	312	319	320
Grade 3 Irritability, Dose 2	52	35	44	48
Related Irritability, Dose 2	208	198	194	212
Any Loss of appetite, Dose 2	164	185	183	179
Grade 3 Loss of appetite, Dose 2	10	6	6	7
Related Loss of appetite, Dose 2	95	103	93	106
Any Temperature, Dose 2	146	145	158	144
Grade 3 Temperature, Dose 2	1	0	1	1
Related Temperature, Dose 2	107	105	116	110
Any Drowsiness, Dose 3	181	194	197	193
Grade 3 Drowsiness, Dose 3	21	7	13	14
Related Drowsiness, Dose 3	112	115	109	112
Any Irritability, Dose 3	259	279	271	262
Grade 3 Irritability, Dose 3	37	30	32	39
Related Irritability, Dose 3	165	178	164	174
Any Loss of appetite, Dose 3	149	176	159	154
Grade 3 Loss of appetite, Dose 3	14	11	10	9
Related Loss of appetite, Dose 3	88	94	83	90
Any Temperature, Dose 3	106	127	112	114
Grade 3 Temperature, Dose 3	0	2	2	1
Related Temperature, Dose 3	71	88	79	89
Any Drowsiness, Across doses	376	365	370	377
Grade 3 Drowsiness, Across doses	45	41	40	47
Related Drowsiness, Across doses	235	231	235	237
Any Irritability, Across doses	419	436	439	441
Grade 3 Irritability, Across doses	109	83	86	104
Related Irritability, Across doses	302	304	311	325
Any Loss of appetite, Across doses	295	325	307	312

Grade 3 Loss of appetite, Across doses	28	23	22	22
Related Loss of appetite, Across doses	180	194	186	182
Any Temperature, Across doses	272	274	277	275
Grade 3 Temperature, Across doses	1	2	3	2
Related Temperature, Across doses	203	208	208	220

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited general symptoms

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and temperature [defined as rectal temperature greater than or equal to (≥) 38 degrees Celsius (°C)]. Any = occurrence of any general symptoms, regardless of their intensity grade or relationship to study vaccination. Grade 3 Drowsiness = Drowsiness that prevented normal activity. Grade 3 Irritability = Crying that could not be comforted/prevented normal activity. Grade 3 Loss of appetite = Not eating at all. Grade 3 Temperature= temperature above 40.0 (°C). Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	491	510	496	504
Units: Participants				
Any Drowsiness	198	206	208	202
Grade 3 Drowsiness	14	13	21	18
Related Drowsiness	125	129	119	125
Any Irritability	284	296	284	297
Grade 3 Irritability	41	37	37	45
Related Irritability	180	197	181	186
Any Loss of appetite	189	193	198	195
Grade 3 Loss of appetite	12	21	23	27
Related Loss of appetite	118	114	114	121
Any Temperature (Rectally)	187	180	186	170
Grade 3 Temperature (Rectally)	2	2	3	7
Related Temperature (Rectally)	133	132	122	125

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited adverse events (AEs)

End point title	Number of subjects with any unsolicited adverse events (AEs)

End point description:

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

End point type	Secondary

End point timeframe:

Within 31-days (Days 0-30) post-booster vaccination period

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	497	511	503	506
Units: Participants	179	185	164	167

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs) from Day 0 to Month 16

End point title	Number of subjects with serious adverse events (SAEs) from Day 0 to Month 16

End point description:

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

End point type	Secondary

End point timeframe:

Throughout the entire study (from Day 0 to Month 16)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	528	524	516	527
Units: Participants				
From Day 0 up to Month 1 post-primary vaccination	1	0	0	0
From primary vaccination up to ESFU contact	54	56	45	52

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)

End point description:

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

End point type	Secondary

End point timeframe:

From Booster vaccination (Month 10) up to Extended Safety Follow-Up (ESFU) (Month 16)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	497	511	503	506
Units: Participants	14	18	14	17

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with new onset of chronic illnesses (NOCIs) from Day 0 to Month 16

End point title	Number of subjects with new onset of chronic illnesses (NOCIs) from Day 0 to Month 16

End point description:

NOCIs assessed included asthma, autoimmune disorders, type 1 diabetes and allergies.

End point type	Secondary

End point timeframe:

During 31-days (Days 0-30) post-each primary vaccination dose (Day 0 to Month 3) and from primary vaccination up to ESFU (Month 16)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	528	524	516	527
Units: Participants				
Day 0 - Day 30 after each primary dose	11	6	5	5
From primary vaccination up to ESFU contact	14	11	15	11

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)

End point description:

NOCIs assessed included asthma, autoimmune disorders, type 1 diabetes and allergies.

End point type	Secondary

End point timeframe:

From Booster vaccination (Month 10 to Month 11) up to ESFU (Month 16)

End point values	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group	NeisVac-C Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	497	511	503	506
Units: Participants	2	2	5	3

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 8-day (Days 0-7) period after each vaccination. Unsolicited AEs: during the 31-day (Days 0-30) period after each vaccination. SAEs: throughout the entire study (Day 0-Extended Safety Follow-up at Month 16).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Nimenrix 3 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 3 primary doses of Nimenrix™ vaccine at 2, 3 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 3, 4 and 12 months of age.

Reporting group title	Nimenrix 2 Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Nimenrix™ vaccine at 2 and 4 months of age, followed by a booster dose of Nimenrix™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of Menjugate® vaccine at 2 and 4 months of age, followed by a booster dose of Menjugate® vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Reporting group title	NeisVac-C Group

Reporting group description:

Healthy male or female subjects aged between and including, 6 and 12 weeks of age, intramuscularly received 2 primary doses of NeisVac-C™ vaccine at 2 and 4 months of age, followed by a booster dose of NeisVac-C™ vaccine at 12 months of age. Subjects were also administered intramuscular injections of Infanrix™ hexa and Synflorix™ vaccines at 2, 4 and 12 months of age.

Serious adverse events	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group
Total subjects affected by serious adverse events			
subjects affected / exposed	54 / 528 (10.23%)	56 / 524 (10.69%)	45 / 516 (8.72%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebral haemangioma			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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

Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 528 (0.00%)	5 / 524 (0.95%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Milk allergy			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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			
Balanoposthitis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular retraction			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Respiratory, thoracic and mediastinal disorders			
Apparent life threatening event			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Asphyxia			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Asthma			

subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Bronchial hyperreactivity			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngospasm			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Rhinitis allergic			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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

Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	4 / 516 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 528 (0.19%)	1 / 524 (0.19%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Near drowning			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Skull fracture			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Thermal burn			
subjects affected / exposed	2 / 528 (0.38%)	1 / 524 (0.19%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital, familial and genetic disorders			
Laryngomalacia			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plagiocephaly			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Cardiac disorders			
Wolff-parkinson-white syndrome			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain injury			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Epilepsy			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			

subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 528 (0.00%)	2 / 524 (0.38%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Enteritis			
subjects affected / exposed	0 / 528 (0.00%)	3 / 524 (0.57%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Inguinal hernia			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia, obstructive			

subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Vomiting			
subjects affected / exposed	2 / 528 (0.38%)	1 / 524 (0.19%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Urticaria			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Muscle spasms			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sacroiliitis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Anal abscess			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Atypical pneumonia			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Bacteraemia			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Bronchiolitis			

subjects affected / exposed	12 / 528 (2.27%)	10 / 524 (1.91%)	9 / 516 (1.74%)
occurrences causally related to treatment / all	0 / 12	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	9 / 528 (1.70%)	4 / 524 (0.76%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 11	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Conjunctivitis			
subjects affected / exposed	1 / 528 (0.19%)	1 / 524 (0.19%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis bacterial			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Croup infectious			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Encephalitis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Epstein-barr virus infection			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Escherichia urinary tract infection			

subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Exanthema subitum			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Gastroenteritis			
subjects affected / exposed	6 / 528 (1.14%)	3 / 524 (0.57%)	5 / 516 (0.97%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Gastroenteritis rotavirus			
subjects affected / exposed	2 / 528 (0.38%)	2 / 524 (0.38%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital candidiasis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
H1n1 influenza			

subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Influenza			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Intervertebral discitis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Laryngitis			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Lung infection			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Nasopharyngitis			
subjects affected / exposed	0 / 528 (0.00%)	2 / 524 (0.38%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			

subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Oral herpes			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Osteomyelitis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Otitis media			
subjects affected / exposed	3 / 528 (0.57%)	0 / 524 (0.00%)	2 / 516 (0.39%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Pertussis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Pharyngitis			
subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Pneumonia			
subjects affected / exposed	4 / 528 (0.76%)	3 / 524 (0.57%)	6 / 516 (1.16%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Pyelonephritis			
subjects affected / exposed	1 / 528 (0.19%)	1 / 524 (0.19%)	1 / 516 (0.19%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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 syncytial virus bronchiolitis			
subjects affected / exposed	2 / 528 (0.38%)	3 / 524 (0.57%)	2 / 516 (0.39%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Rotavirus infection			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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
Sepsis			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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
Tonsillitis			

subjects affected / exposed	1 / 528 (0.19%)	0 / 524 (0.00%)	0 / 516 (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
Upper respiratory tract infection			
subjects affected / exposed	4 / 528 (0.76%)	2 / 524 (0.38%)	2 / 516 (0.39%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	3 / 528 (0.57%)	1 / 524 (0.19%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	2 / 528 (0.38%)	0 / 524 (0.00%)	0 / 516 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	0 / 528 (0.00%)	1 / 524 (0.19%)	0 / 516 (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			
Decreased appetite			
subjects affected / exposed	0 / 528 (0.00%)	0 / 524 (0.00%)	0 / 516 (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

Serious adverse events	NeisVac-C Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	52 / 527 (9.87%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cerebral haemangioma			

subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 527 (0.57%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular retraction			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Apparent life threatening event			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asphyxia			

subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchial hyperreactivity				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngospasm				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis allergic				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Breath holding				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Alanine aminotransferase increased				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase				

increased				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood alkaline phosphatase increased				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Concussion				
subjects affected / exposed	2 / 527 (0.38%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Contusion				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Near drowning				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Thermal burn				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Laryngomalacia				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plagiocephaly				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Wolff-parkinson-white syndrome				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain injury				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile convulsion				
subjects affected / exposed	2 / 527 (0.38%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypotonia				

subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Inguinal hernia			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia, obstructive			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis			

subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Muscle spasms				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sacroiliitis				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Torticollis				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenovirus infection				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atypical pneumonia				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				

subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial pyelonephritis				
subjects affected / exposed	2 / 527 (0.38%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	14 / 527 (2.66%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	8 / 527 (1.52%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Conjunctivitis				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Conjunctivitis bacterial				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Croup infectious				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				

subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epstein-barr virus infection				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Exanthema subitum				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	3 / 527 (0.57%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis bacterial				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus				
subjects affected / exposed	2 / 527 (0.38%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				

subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Genital candidiasis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
H1n1 influenza			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes simplex			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung infection			

subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral candidiasis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oral herpes			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	2 / 527 (0.38%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pertussis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			

subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	5 / 527 (0.95%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	4 / 527 (0.76%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 527 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection				
subjects affected / exposed	1 / 527 (0.19%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				

subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	2 / 527 (0.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral rash			
subjects affected / exposed	0 / 527 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 527 (0.19%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Nimenrix 3 Group	Nimenrix 2 Group	Menjugate Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	512 / 528 (96.97%)	516 / 524 (98.47%)	506 / 516 (98.06%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	398 / 528 (75.38%)	386 / 524 (73.66%)	399 / 516 (77.33%)
occurrences (all)	909	892	921
General disorders and administration site conditions			
Pain			
subjects affected / exposed	386 / 528 (73.11%)	379 / 524 (72.33%)	394 / 516 (76.36%)
occurrences (all)	895	899	927
Pyrexia			
subjects affected / exposed	348 / 528 (65.91%)	348 / 524 (66.41%)	349 / 516 (67.64%)
occurrences (all)	627	647	660
Swelling			
subjects affected / exposed	376 / 528 (71.21%)	380 / 524 (72.52%)	391 / 516 (75.78%)
occurrences (all)	858	864	924
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	34 / 528 (6.44%)	31 / 524 (5.92%)	32 / 516 (6.20%)
occurrences (all)	37	39	42
Vomiting			
subjects affected / exposed	24 / 528 (4.55%)	20 / 524 (3.82%)	26 / 516 (5.04%)
occurrences (all)	27	22	28
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	411 / 528 (77.84%)	412 / 524 (78.63%)	432 / 516 (83.72%)
occurrences (all)	1036	1079	1139
Psychiatric disorders			
Irritability			
subjects affected / exposed	446 / 528 (84.47%)	457 / 524 (87.21%)	455 / 516 (88.18%)
occurrences (all)	1205	1230	1238
Infections and infestations			
Bronchiolitis			

subjects affected / exposed	34 / 528 (6.44%)	29 / 524 (5.53%)	31 / 516 (6.01%)
occurrences (all)	39	32	33
Bronchitis			
subjects affected / exposed	45 / 528 (8.52%)	31 / 524 (5.92%)	34 / 516 (6.59%)
occurrences (all)	49	35	37
Conjunctivitis			
subjects affected / exposed	27 / 528 (5.11%)	21 / 524 (4.01%)	31 / 516 (6.01%)
occurrences (all)	28	24	32
Gastroenteritis			
subjects affected / exposed	31 / 528 (5.87%)	31 / 524 (5.92%)	21 / 516 (4.07%)
occurrences (all)	32	32	22
Nasopharyngitis			
subjects affected / exposed	25 / 528 (4.73%)	28 / 524 (5.34%)	33 / 516 (6.40%)
occurrences (all)	30	30	42
Rhinitis			
subjects affected / exposed	33 / 528 (6.25%)	31 / 524 (5.92%)	40 / 516 (7.75%)
occurrences (all)	39	34	41
Upper respiratory tract infection			
subjects affected / exposed	108 / 528 (20.45%)	118 / 524 (22.52%)	108 / 516 (20.93%)
occurrences (all)	146	166	162
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	361 / 528 (68.37%)	367 / 524 (70.04%)	355 / 516 (68.80%)
occurrences (all)	692	762	738

Non-serious adverse events	NeisVac-C Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	513 / 527 (97.34%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	408 / 527 (77.42%)		
occurrences (all)	903		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	379 / 527 (71.92%)		
occurrences (all)	892		
Pyrexia			

subjects affected / exposed	343 / 527 (65.09%)		
occurrences (all)	645		
Swelling			
subjects affected / exposed	372 / 527 (70.59%)		
occurrences (all)	890		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	32 / 527 (6.07%)		
occurrences (all)	35		
Vomiting			
subjects affected / exposed	13 / 527 (2.47%)		
occurrences (all)	15		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	412 / 527 (78.18%)		
occurrences (all)	1100		
Psychiatric disorders			
Irritability			
subjects affected / exposed	460 / 527 (87.29%)		
occurrences (all)	1247		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	37 / 527 (7.02%)		
occurrences (all)	43		
Bronchitis			
subjects affected / exposed	48 / 527 (9.11%)		
occurrences (all)	56		
Conjunctivitis			
subjects affected / exposed	31 / 527 (5.88%)		
occurrences (all)	34		
Gastroenteritis			
subjects affected / exposed	18 / 527 (3.42%)		
occurrences (all)	18		
Nasopharyngitis			
subjects affected / exposed	30 / 527 (5.69%)		
occurrences (all)	35		
Rhinitis			

subjects affected / exposed	21 / 527 (3.98%)		
occurrences (all)	24		
Upper respiratory tract infection			
subjects affected / exposed	103 / 527 (19.54%)		
occurrences (all)	135		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	370 / 527 (70.21%)		
occurrences (all)	747		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 December 2010	An inconsistency between inclusion criteria and Table 5 was noticed and Table 5 has been corrected according to inclusion criteria. The age for administration of the booster dose has been clarified. Procedure for reporting Guillain Barre syndrome (GBS) has been added. New cold chain deviation wording has been incorporated.
25 May 2011	The sample size of the study population is increased by approximately 50%, i.e., 680 additional subjects will be enrolled in the study to reach the target samples size of 1650 evaluable subjects to demonstrate the co-primary objectives of this study. The serum bactericidal assay (SBA) is a functional measure of the ability of antibodies in conjunction with complement to kill bacteria and is considered the assay of choice for measurement of functional anti-meningococcal antibodies in vitro. It is well known that, as there is no standardized SBA testing, the interlaboratory variability could have an important impact on the measured bactericidal titers. Depending on the laboratory where the SBA testing is to be performed, differences around 1% in the percentage of subjects with seroprotective titers may occur. It has been estimated that 50% sample size increase would be necessary to demonstrate all the sequential co-primary objectives regardless of the laboratory where the testing is performed. The primary endpoint of the current study is to assess the immunogenicity induced by the components of the investigational vaccine in terms of rSBA titres ≥ 1:8 for each of the four serogroups (A, C, W-135 and Y) in all subjects, one month after the final priming vaccination. In addition, rSBA titres ≥ 1:8 and ≥ 1:128 will also be assessed at any blood sampling time point during the study in a subset of subjects in all vaccine groups as secondary endpoints. To support the data obtained by rSBA testing, hSBA testing will also be performed and in addition antibody concentrations against meningococcal polysaccharides (PS) are planned to be assessed by ELISA (anti-PS testing). Now, GSK Biologicals decided not to perform anti-PS testing at any blood sampling time point 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].
30 July 2012	A measles outbreak in Spain impacted 2 centers participating in the study and the local authorities recommended vaccinating subjects from 9 months old onwards. The protocol is amended to allow administration of Measles, Mumps, Rubella (MMR) or Measles, Mumps, Rubella and Varicella (MMRV) vaccine throughout the study in line with local governmental recommendations. It is preferable that the vaccine not be given within 30 days prior or after a dose of study vaccine (with the day of vaccination considered Day 0). The introduction was updated with the current licensing status of MenACWY-TT and competitor vaccines. Several sections were updated to clarify that the Immune Mediated Disease (IMD) report should only be used in case of Guillain-Barre syndrome (GBS).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported