Clinical trial results:
A phase IIb, open, randomised, controlled primary vaccination study to evaluate the non-inferiority and the persistence of the immune response of GSK Biologicals' meningococcal serogroup ACWY conjugate vaccine given intramuscularly versus Mencevax ACWY given subcutaneously to healthy subjects aged 11 to 55 years of age

Summary

EudraCT number	2012-002722-75
Trial protocol	Outside EU/EEA
Global end of trial date	16 February 2013

Results information

Result version number	v3 (current)
This version publication date	24 June 2022
First version publication date	18 July 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	107386

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00356369
WHO universal trial number (UTN)	-
Other trial identifiers	107392: eTrack number, 107398: eTrack number, 107402: eTrack number, 107404: eTrack number, 107406: eTrack number

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 June 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 February 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

One month after vaccination:
• To evaluate the non-inferiority of the vaccine response induced by the MenACWY TT conjugate vaccine when compared to the licensed Mencevax ACWY.
• To evaluate the non-inferiority of the MenACWY-TT conjugate vaccine when compared to the licensed Mencevax ACWY in terms of the incidence of any grade 3 systemic symptom within 4 days after vaccination.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 December 2006
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 400
Country: Number of subjects enrolled	Saudi Arabia: 100
Worldwide total number of subjects	500
EEA total number of subjects	0

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)	0
Children (2-11 years)	43
Adolescents (12-17 years)	258
Adults (18-64 years)	199
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	Active Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

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

Dosage and administration details:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine, MenACWY
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 1	Nimenrix Group	Mencevax Group
Started	374	126
Completed	372	125
Not completed	2	1
Consent withdrawn by subject	2	1

Period 2

Period 2 title	Year 1
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	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:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 2[1]	Nimenrix Group	Mencevax Group
Started	364	121
Completed	364	121

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

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

Period 3

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	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:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 3[2]	Nimenrix Group	Mencevax Group
Started	354	117
Completed	354	117

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

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

Period 4

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	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:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 4[3]	Nimenrix Group	Mencevax Group
Started	344	116
Completed	344	116

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

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

Period 5

Period 5 title	Year 4
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	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:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 5[4]	Nimenrix Group	Mencevax Group
Started	317	109
Completed	317	109

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

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

Period 6

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	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:

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

Arm title	Mencevax Group

Arm description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Arm type	Active comparator
Investigational medicinal product name	Mencevax
Investigational medicinal product code	
Other name	GSK Biologicals' meningococcal serogroups A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

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

Number of subjects in period 6[5]	Nimenrix Group	Mencevax Group
Started	299	105
Completed	299	105

Notes:

[5] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

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

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix Group
Reporting group description:	
Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.	

Reporting group values	Nimenrix Group	Mencevax Group	Total
Number of subjects	374	126	500
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)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	374	126	500
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	18.6	19.3	
standard deviation	± 7.62	± 8.58	-
Gender categorical Units: Subjects			
Female	168	60	228
Male	206	66	272

End points

End points reporting groups

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) by injection in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Primary: Vaccine response to meningococcal antigens for serum bactericidal assay using rabbit complement (rSBA)

End point title	Vaccine response to meningococcal antigens for serum bactericidal assay using rabbit complement (rSBA)

End point description:

Response to vaccine antigen was defined as: for initially seronegative subjects [subjects with serum bactericidal assay using rabbit complement (rSBA) titer lower than (<) 1:8], post-vaccination rSBA titer greater than or equal to (≥) 1:32 and for initially seropositive (subjects with rSBA titer ≥ 1:8), at least 4-fold increase in rSBA titer from pre to post vaccination.

End point type	Primary

End point timeframe:

One Month post vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	329	113		
Units: percentage of subjects				
number (confidence interval 95%)				
rSBA-MenA [N=289;99]	82.7 (77.8 to 86.9)	69.7 (59.6 to 78.5)		
rSBA-MenC [N=324;113]	94.4 (91.4 to 96.7)	90.3 (83.2 to 95)		
rSBA-MenW-135 [N=326;109]	96.3 (93.7 to 98.1)	91.7 (84.9 to 96.2)		
rSBA-MenY [N=329;113]	93 (89.7 to 95.5)	85 (77 to 91)		

Statistical analyses

Statistical analysis title	Difference in % for rSBA-MenA antibodies

Statistical analysis description:

To evaluate the non-inferiority of the vaccine response induced by the MenACWY-TT vaccine when compared to the licensed MenACWY vaccine.

Comparison groups	Nimenrix Group v Mencevax Group
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Difference in % for rSBA-MenA antibodies
Point estimate	13
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.52
upper limit	23.5

Notes:

[1] - Criterion indicative of non-inferiority: Lower limit of the standardized asymptotic 95% confidence interval (CI) for the difference between MenACWY-TT and (minus) MenACWY in the percentage of subjects with bactericidal vaccine response was greater than (>) -15%.

Statistical analysis title	Difference in % for rSBA-MenC antibodies

Statistical analysis description:

To evaluate the non-inferiority of the vaccine response induced by the MenACWY-TT vaccine when compared to the licensed MenACWY vaccine.

Comparison groups	Nimenrix Group v Mencevax Group
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in % for rSBA-MenC antibodies
Point estimate	4.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.03
upper limit	11.36

Notes:

[2] - Criterion indicative of non-inferiority: Lower limit of the standardized asymptotic 95% confidence interval (CI) for the difference between MenACWY-TT and (minus) MenACWY in the percentage of subjects with bactericidal vaccine response was ≥ -12%.

Statistical analysis title	Difference in % for rSBA-MenW antibodies

Statistical analysis description:

To evaluate the non-inferiority of the vaccine response induced by the MenACWY-TT vaccine when compared to the licensed MenACWY vaccine.

Comparison groups	Nimenrix Group v Mencevax Group
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in % for rSBA-MenW-135 antibo
Point estimate	4.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.07
upper limit	11.49

Notes:

[3] - Criterion indicative of non-inferiority: Lower limit of the standardized asymptotic 95% confidence interval (CI) for the difference between MenACWY-TT and (minus) MenACWY in the percentage of subjects with bactericidal vaccine response was ≥ -12%.

Statistical analysis title	Difference in % for rSBA-MenY antibodies

Statistical analysis description:

To evaluate the non-inferiority of the vaccine response induced by the MenACWY-TT vaccine when compared to the licensed MenACWY vaccine.

Comparison groups	Nimenrix Group v Mencevax Group
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in % for rSBA-MenY antibodies
Point estimate	8.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.72
upper limit	16.17

Notes:

[4] - Criterion indicative of non-inferiority: Lower limit of the standardized asymptotic 95% confidence interval (CI) for the difference between MenACWY-TT and (minus) MenACWY in the percentage of subjects with bactericidal vaccine response was ≥ -12%.

Primary: Number of subjects with Grade 3 symptoms

End point title	Number of subjects with Grade 3 symptoms

End point description:

Local symptom, Grade 3 = pain that prevented normal activity and redness/ swelling spreading beyond (>) 50 millimeters (mm). General symptom, Grade 3 = any general symptom that prevented normal activity including fever (orally) >39.5 °C.

End point type	Primary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects				
Any Grade 3 unsolicited	12	1		
Grade 3 solicited general	5	0		
Grade 3 solicited local	9	1		

Statistical analyses

Statistical analysis title	Difference in % Grade 3 general symptoms

Statistical analysis description:

To evaluate the non-inferiority of the MenACWY-TT conjugate vaccine when compared to the licensed MenACWY vaccine in terms of the incidence of any Grade 3 systemic symptom within 4 days after vaccination.

Comparison groups	Nimenrix Group v Mencevax Group
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in % Grade 3 general symptoms
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.64
upper limit	3.09

Notes:

[5] - Criterion indicative of non-inferiority: Upper limit of the standardized asymptotic 95% CI on the difference between MenACWY- TT and (minus) MenACWY in the incidence of Grade 3 systemic symptoms was below 5%.

Secondary: Number of subjects with serum bactericidal assay using rabbit complement against Neisseria meningitidis serogroups A, C, W-135, Y (rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY) antibody titers ≥ the cut-off value

End point title	Number of subjects with serum bactericidal assay using rabbit complement against Neisseria meningitidis serogroups A, C, W-135, Y (rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY) antibody titers ≥ the cut-off value

End point description:

The cut-off value for the rSBA titers was greater than or equal to (≥) 1:8 and (≥) 1:128.

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	114		
Units: Subjects				
rSBA-MenA (PRE) ≥ 1:8 [N=305;101]	290	88		
rSBA-MenA (PI [M1]) ≥ 1:8 [N=323;112]	323	112		
rSBA-MenA (PRE) ≥ 1:128 [N=305;101]	273	81		
rSBA-MenA (PI [M1]) ≥ 1:128 [N=323;112]	322	112		
rSBA-MenC (PRE) ≥ 1:8 [N=324;113]	253	96		
rSBA-MenC (PI [M1]) ≥ 1:8 [N=341;114]	340	114		
rSBA-MenC (PRE) ≥ 1:128 [N=324;113]	172	56		
rSBA-MenC (PI [M1]) ≥ 1:128 [N=341;114]	340	112		
rSBA-MenW-135 (PRE) ≥ 1:8 [N=327;109]	247	89		
rSBA-MenW-135 (PI [M1]) ≥ 1:8 [N=340;114]	339	114		
rSBA-MenW-135 (PRE) ≥ 1:128 [N=327;109]	191	67		
rSBA-MenW-135 (PI [M1]) ≥ 1:128 [N=340;114]	338	114		
rSBA-MenY (PRE) ≥ 1:8 [N=330;113]	306	105		
rSBA-MenY (PI [M1]) ≥ 1:8 [N=340;114]	340	114		
rSBA-MenY (PRE) ≥ 1:128 [N=330;113]	264	88		
rSBA-MenY (PI [M1]) ≥ 1:128 [N=340;114]	339	114		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres

End point description:

Antibody titers are presented as Geometric Mean Titers (GMTs).

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	114		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PRE) [N=305;101]	330.7 (285.8 to 382.7)	227.8 (162.1 to 320.2)		
rSBA-MenA (PI [M1]) [N=323;112]	4944.6 (4451.5 to 5492.5)	2190.1 (1857.5 to 2582.2)		
rSBA-MenC (PRE) [N=324;113]	84.1 (68.5 to 103.4)	114.1 (80.3 to 162)		
rSBA-MenC (PI [M1]) [N=341;114]	10073.7 (8699.9 to 11664.5)	6545.6 (5047.5 to 8488.4)		
rSBA-MenW-135 (PRE) [N=327;109]	93 (74.6 to 116)	115.3 (81.6 to 162.9)		
rSBA-MenW-135 (PI [M1]) [N=340;114]	8576.5 (7614.9 to 9659.5)	2969.5 (2439.4 to 3614.9)		
rSBA-MenY (PRE) [N=330;113]	310 (261.2 to 367.9)	282.8 (209.9 to 380.8)		
rSBA-MenY (PI [M1]) [N=340;114]	10315.2 (9317.1 to 11420.2)	4573.7 (3863.9 to 5413.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-Polysaccharide (anti-PS) antibodies

End point title	Number of subjects with anti-Polysaccharide (anti-PS) antibodies

End point description:

The cut-off value for the anti-PS concentration was greater than or equal to (≥) 0.3 micrograms per milliliter (µg/mL) and ≥ 2.0 µg/mL.

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	114		
Units: Subjects				
Anti-PSA (PRE) ≥ 0.3 µg/mL [N=316;107]	255	90		
Anti-PSA (PI [M1]) ≥ 0.3 µg/mL [N=340;113]	339	113		
Anti-PSA (PRE) ≥ 2.0 µg/mL [N=316;107]	137	53		
Anti-PSA (PI [M1]) ≥ 2.0 µg/mL [N=340;113]	339	113		
Anti-PSC (PRE) ≥ 0.3 µg/mL [N=334;110]	71	27		
Anti-PSC (PI M1]) ≥ 0.3 µg/mL [N=341;114]	340	114		
Anti-PSC (PRE) ≥ 2.0 µg/mL [N=334;110]	30	16		
Anti-PSC (PI [M1]) ≥ 2.0 µg/mL [N=341;114]	333	113		
Anti-PSW-135 (PRE) ≥ 0.3 µg/mL [N=332;106]	41	17		
Anti-PSW-135 (PI M1]) ≥ 0.3 µg/mL [N=339;114]	335	113		
Anti-PSW-135 (PRE) ≥ 2.0 µg/mL [N=332;106]	11	4		
Anti-PSW-135 (PI [M1]) ≥ 2.0 µg/mL [N=339;114]	314	106		
Anti-PSY (PRE) ≥ 0.3 µg/mL [N=329;110]	55	23		
Anti-PSY (PI M1]) ≥ 0.3 µg/mL [N=339;112]	338	112		
Anti-PSY (PRE) ≥ 2.0 µg/mL [N=329;110]	25	8		
Anti-PSY (PI [M1]) ≥ 2.0 µg/mL [N=339;112]	328	109		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of anti-PS antibodies

End point title	Concentration of anti-PS antibodies

End point description:

Antibody concentrations were expressed as Geometric Mean Concentrations (GMCs) and measured in micrograms/milliliter (µg/mL).

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	114		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PRE) [N=316;107]	1.4 (1.2 to 1.7)	1.7 (1.3 to 2.3)		
Anti-PSA (PI [M1]) [N=340;113]	107.3 (92.7 to 124.1)	53.6 (41.9 to 68.5)		
Anti-PSC (PRE) [N=334;110]	0.3 (0.2 to 0.3)	0.3 (0.2 to 0.4)		
Anti-PSC (PI M1]) [N=341;114]	23.9 (21 to 27.2)	43.9 (35.6 to 54.1)		
Anti-PSW-135 (PRE) [N=332;106]	0.2 (0.2 to 0.2)	0.2 (0.2 to 0.3)		
Anti-PSW-135 (PI M1]) [N=339;114]	18.6 (15.8 to 21.8)	15.8 (12.1 to 20.7)		
Anti-PSY (PRE) [N=329;110]	0.2 (0.2 to 0.3)	0.2 (0.2 to 0.3)		
Anti-PSY (PI M1]) [N=339;112]	23.2 (19.9 to 26.9)	23.6 (18.4 to 30.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-Tetanus (anti-TT) antibodies ≥ the cut-off value

End point title	Number of subjects with anti-Tetanus (anti-TT) antibodies ≥ the cut-off value

End point description:

Cut-off values assessed were ≥ 0.1 international units per milliliter (IU/mL).

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	113		
Units: Subjects				
Anti-TT (PRE) [N=331;110]	223	110		
Anti-TT (PI [M1]) [N=341;113]	326	113		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of anti-TT antibodies

End point title	Concentration of anti-TT antibodies

End point description:

Concentrations were presented as GMCs expressed in international units per milliliter.

End point type	Secondary

End point timeframe:

At pre-vaccination at Day 0 (PRE) and post-vaccination at Month 1 (PI[M1])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	113		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-TT (PRE) [N=331;110]	0.35 (0.29 to 0.43)	0.28 (0.2 to 0.39)		
Anti-TT (PI [M1]) [N=341;113]	10.01 (8.34 to 12.03)	0.27 (0.19 to 0.38)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The cut-off value for the rSBA titres was greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Year 1 (PI[M12])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	356	117		
Units: Subjects				
rSBA-MenA (PI [M12]) ≥ 1:8 [N=354;113]	353	113		
rSBA-MenA (PI [M12]) ≥ 1:128 [N=354;113]	352	112		

rSBA-MenC (PI [M12]) ≥ 1:8 [N=353;115]	352	114		
rSBA-MenC (PI [M12]) ≥ 1:128 [N=353;115]	343	110		
rSBA-MenW-135 (PI [M12]) ≥ 1:8 [N=356;117]	355	117		
rSBA-MenW-135 (PI [M12]) ≥ 1:128 [N=356;117]	354	111		
rSBA-MenY (PI [M12]) ≥ 1:8 [N=355;116]	355	116		
rSBA-MenY (PI [M12]) ≥ 1:128 [N=355;116]	354	114		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres

End point description:

Antibody titers are presented as Geometric Mean Titers (GMTs).

End point type	Secondary

End point timeframe:

At Year 1 (PI[M12])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	356	117		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI [M12]) [N=354;113]	2084.9 (1888.3 to 2302)	1099.1 (931.6 to 1296.7)		
rSBA-MenC (PI [M12]) [N=353;115]	1848.6 (1620.3 to 2109.2)	1876.5 (1400.7 to 2514)		
rSBA-MenW-135 (PI [M12]) [N=356;117]	2993.5 (2618.8 to 3421.9)	699.9 (569.3 to 860.4)		
rSBA-MenY (PI [M12]) [N=355;116]	4207.1 (3767.3 to 4698.3)	1386.5 (1104.2 to 1740.9)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The cut-off value for the rSBA titers was greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Year 2 (PI[M24])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	346	112		
Units: Subjects				
rSBA-MenA (PI [M24]) ≥ 1:8 [N=338;102]	337	101		
rSBA-MenA (PI [M24]) ≥ 1:128 [N=338;102]	335	98		
rSBA-MenC (PI [M24]) ≥ 1:8 [N=345;112]	343	110		
rSBA-MenC (PI [M24]) ≥ 1:128 [N=345;112]	332	103		
rSBA-MenW-135 (PI [M24]) ≥ 1:8 [N=346;111]	344	100		
rSBA-MenW-135 (PI [M24]) ≥ 1:128 [N=346;111]	341	90		
rSBA-MenY (PI [M24]) ≥ 1:8 [N=345;111]	344	110		
rSBA-MenY (PI [M24]) ≥ 1:128 [N=345;111]	342	105		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres

End point description:

Antibody titers are presented as Geometric Mean Titers.

End point type	Secondary

End point timeframe:

At Year 2 (PI[M24])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	346	112		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI [M24]) [N=338;102]	1326.8 (1197.7 to 1469.7)	698.9 (561.2 to 870.4)		
rSBA-MenC (PI [M24]) [N=345;112]	1162 (1013.1 to 1332.9)	1229.4 (876.4 to 1724.7)		
rSBA-MenW-135 (PI [M24]) [N=346;111]	1984.6 (1757.1 to 2241.4)	319.1 (228 to 446.5)		
rSBA-MenY (PI [M24]) [N=345;111]	3042.1 (2692.2 to 3437.5)	850.2 (667.5 to 1082.9)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The cut-off value for the rSBA titers was greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Year 3 (PI[M36])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	338	109		
Units: Subjects				
rSBA-MenA (PI [M36]) ≥ 1:8 [N=322;104]	322	104		
rSBA-MenA (PI [M36]) ≥ 1:128 [N=322;104]	319	98		
rSBA-MenC (PI [M36]) ≥ 1:8 [N=337;109]	334	108		
rSBA-MenC (PI [M36]) ≥ 1:128 [N=337;109]	313	102		
rSBA-MenW-135 (PI [M36]) ≥ 1:8 [N=336;105]	335	91		
rSBA-MenW-135 (PI [M36]) ≥ 1:128 [N=336;105]	332	84		
rSBA-MenY (PI [M36]) ≥ 1:8 [N=338;108]	337	107		

rSBA-MenY (PI [M36]) ≥ 1:128 [N=338;108]	336	105		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres

End point description:

Antibody titers are presented as Geometric Mean Titers.

End point type	Secondary

End point timeframe:

At Year 3 (PI[M36])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	338	109		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI [M36]) [N=322;104]	1238.4 (1126 to 1361.9)	596.9 (488.5 to 729.3)		
rSBA-MenC (PI [M36]) [N=337;109]	870.3 (757.1 to 1000.4)	1124.8 (812.3 to 1557.6)		
rSBA-MenW-135 (PI [M36]) [N=336;105]	2109.2 (1842.5 to 2414.5)	332.8 (224.4 to 493.8)		
rSBA-MenY (PI [M36]) [N=338;108]	2567.3 (2288.6 to 2879.8)	848 (682.6 to 1053.5)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The cut-off value for the rSBA titers was greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Year 4 (PI[M48])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	312	107		
Units: Subjects				
rSBA-MenA (PI [M48]) ≥ 1:8 [N=312;107]	270	79		
rSBA-MenA (PI [M48]) ≥ 1:128 [N=312;107]	245	66		
rSBA-MenC (PI [M48]) ≥ 1:8 [N=312;107]	276	90		
rSBA-MenC (PI [M48]) ≥ 1:128 [N=312;107]	254	79		
rSBA-MenW-135 (PI [M48]) ≥ 1:8 [N=312;107]	231	27		
rSBA-MenW-135 (PI [M48]) ≥ 1:128 [N=312;107]	214	22		
rSBA-MenY (PI [M48]) ≥ 1:8 [N=309;107]	256	47		
rSBA-MenY (PI [M48]) ≥ 1:128 [N=309;107]	243	37		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres
End point description:	
Antibody titers are presented as Geometric Mean Titers.	
End point type	Secondary
End point timeframe:	
At Year 4 (PI[M48])	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	312	107		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI [M48]) [N=312;107]	278.6 (219.7 to 353.2)	105.4 (67.6 to 164.4)		
rSBA-MenC (PI [M48]) [N=312;107]	273.6 (220.6 to 339.4)	315 (196.8 to 504.1)		
rSBA-MenW-135 (PI [M48]) [N=312;107]	175.1 (131.5 to 233)	11.3 (7.8 to 16.3)		

rSBA-MenY (PI [M48]) [N=309;107]	350.5 (268.9 to 456.7)	26 (16.6 to 40.7)		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The cut-off value for the rSBA titers was greater than or equal to (≥) 1:8 and ≥ 1:128.

End point type	Secondary

End point timeframe:

At Year 5 (PI[M60])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	19		
Units: Subjects				
rSBA-MenA (PI [M60]) ≥ 1:8 [N=51;19]	43	11		
rSBA-MenA (PI [M60]) ≥ 1:128 [N=51;19]	39	9		
rSBA-MenC (PI [M60]) ≥ 1:8 [N=51;18]	37	7		
rSBA-MenC (PI [M60]) ≥ 1:128 [N=51;18]	28	5		
rSBA-MenW-135 (PI [M60]) ≥ 1:8 [N=51;19]	44	6		
rSBA-MenW-135 (PI [M60]) ≥ 1:128 [N=51;19]	38	6		
rSBA-MenY (PI [M60]) ≥ 1:8 [N=51;19]	47	12		
rSBA-MenY (PI [M60]) ≥ 1:128 [N=51;19]	47	11		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA antibody titres

End point title	rSBA antibody titres

End point description:

Antibody titers are presented as Geometric Mean Titers.

End point type	Secondary

End point timeframe:

At Year 5 (PI[M60])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	19		
Units: titre				
geometric mean (confidence interval 95%)				
rSBA-MenA (PI [M60]) [N=51;19]	189.8 (107.7 to 334.6)	37 (12.6 to 108.7)		
rSBA-MenC (PI [M60]) [N=51;18]	78.5 (41.8 to 147.4)	17.3 (6 to 49.7)		
rSBA-MenW-135 (PI [M60]) [N=51;19]	281.6 (145.9 to 543.2)	15.4 (5.7 to 41.9)		
rSBA-MenY (PI [M60]) [N=51;19]	769.7 (438.6 to 1351)	74.1 (21.9 to 250.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies

End point title	Number of subjects with anti-PS antibodies

End point description:

The cut-off value for the anti-PS concentration was greater than or equal to (≥) 0.3 µg/mL and ≥ 2.0 µg/mL.

End point type	Secondary

End point timeframe:

At Year 1 (PI[M12])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	117		
Units: Subjects				
Anti-PSA (PI [M12]) ≥ 0.3 µg/mL [N=352;116]	351	116		
Anti-PSA (PI [M12]) ≥ 2.0 µg/mL [N=352;116]	332	115		
Anti-PSC (PI [M12]) ≥ 0.3 µg/mL [N=354;117]	349	117		
Anti-PSC (PI [M12]) ≥ 2.0 µg/mL [N=354;117]	262	113		
Anti-PSW-135 (PI [M12]) ≥ 0.3 µg/mL [N=348;115]	342	112		

Anti-PSW-135 (PI [M12]) ≥ 2.0 µg/mL [N=348;115]	264	102		
Anti-PSY (PI [M12]) ≥ 0.3 µg/mL [N=354;116]	350	116		
Anti-PSY (PI [M12]) ≥ 2.0 µg/mL [N=354;116]	289	110		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of anti-PS antibodies

End point title	Concentration of anti-PS antibodies

End point description:

Antibody concentrations were expressed as Geometric Mean Concentrations and measured in µg/mL.

End point type	Secondary

End point timeframe:

At Year 1 (PI[M12])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	354	117		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PI [M12]) [N=352;116]	23.25 (19.78 to 27.32)	31.72 (24.77 to 40.63)		
Anti-PSC (PI [M12]) [N=354;117]	4.67 (4.08 to 5.33)	24.53 (19.92 to 30.2)		
Anti-PSW-135 (PI [M12]) [N=348;115]	5.48 (4.68 to 6.4)	10.39 (7.8 to 13.85)		
Anti-PSY (PI [M12]) [N=354;116]	6.68 (5.69 to 7.85)	16.7 (12.9 to 21.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies

End point title	Number of subjects with anti-PS antibodies

End point description:

The cut-off value for the anti-PS concentration was greater than or equal to (≥) 0.3 µg/mL and ≥ 2.0 µg/mL.

End point type	Secondary

End point timeframe:

At Year 2 (PI[M24])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	343	112		
Units: Subjects				
Anti-PSA (PI [M24]) ≥ 0.3 µg/mL [N=336;105]	335	105		
Anti-PSA (PI [M24]) ≥ 2.0 µg/mL [N=336;105]	301	103		
Anti-PSC (PI [M24]) ≥ 0.3 µg/mL [N=340;111]	323	111		
Anti-PSC (PI [M24]) ≥ 2.0 µg/mL [N=340;111]	196	107		
Anti-PSW-135 (PI [M24]) ≥ 0.3 µg/mL [N=336;110]	316	108		
Anti-PSW-135 (PI [M24]) ≥ 2.0 µg/mL [N=336;110]	226	93		
Anti-PSY (PI [M24]) ≥ 0.3 µg/mL [N=343;112]	325	110		
Anti-PSY (PI [M24]) ≥ 2.0 µg/mL [N=343;112]	237	97		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of anti-PS antibodies

End point title	Concentration of anti-PS antibodies
End point description:	
Antibody concentrations were expressed as Geometric Mean Concentrations and measured in µg/mL.	
End point type	Secondary
End point timeframe:	
At Year 2 (PI[M24])	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	343	112		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PI [M24]) [N=336;105]	15.15 (12.76 to 17.98)	24.85 (19.08 to 32.36)		
Anti-PSC (PI [M24]) [N=340;111]	2.62 (2.27 to 3.03)	15.74 (12.56 to 19.72)		
Anti-PSW-135 (PI [M24]) [N=336;110]	3.51 (2.98 to 4.15)	6.76 (5.08 to 9.01)		

Anti-PSY (PI [M24]) [N=343;112]	4.44 (3.73 to 5.3)	11.11 (8.39 to 14.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PS antibodies

End point title	Number of subjects with anti-PS antibodies

End point description:

The cut-off value for the anti-PS concentration was greater than or equal to (≥) 0.3 µg/mL and ≥ 2.0 µg/mL.

End point type	Secondary

End point timeframe:

At Year 3 (PI[M36])

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	331	110		
Units: Subjects				
Anti-PSA (PI [M36]) ≥ 0.3 µg/mL [N=330;109]	328	109		
Anti-PSA (PI [M36]) ≥ 2.0 µg/mL [N=330;109]	300	108		
Anti-PSC (PI [M36]) ≥ 0.3 µg/mL [N=331;110]	318	110		
Anti-PSC (PI [M36]) ≥ 2.0 µg/mL [N=331;110]	200	106		
Anti-PSW-135 (PI [M36]) ≥ 0.3 µg/mL [N=328;108]	303	105		
Anti-PSW-135 (PI [M36]) ≥ 2.0 µg/mL [N=328;108]	204	87		
Anti-PSY (PI [M36]) ≥ 0.3 µg/mL [N=323;110]	299	108		
Anti-PSY (PI [M36]) ≥ 2.0 µg/mL [N=323;110]	213	92		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of anti-PS antibodies

End point title	Concentration of anti-PS antibodies

End point description:

Antibody concentrations were expressed as Geometric Mean Concentrations and measured in µg/mL.

End point type	Secondary
End point timeframe: At Year 3 (PI[M36])	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	331	110		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA (PI [M36]) N=330;109]	12.5 (10.7 to 14.6)	19.8 (15.7 to 24.9)		
Anti-PSC (PI [M36]) [N=331;110]	2.7 (2.3 to 3)	13.9 (11.2 to 17.2)		
Anti-PSW-135 (PI [M36]) [N=328;108]	2.9 (2.5 to 3.4)	5.5 (4.2 to 7.2)		
Anti-PSY (PI [M36]) [N=323;110]	3.8 (3.2 to 4.5)	8.2 (6.2 to 10.8)		

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 = pain that prevented normal activity. Grade 3 Redness/Swelling = redness/swelling spreading beyond 50 millimeters (mm) of injection site.	
End point type	Secondary
End point timeframe: During the 4-day (Days 0-3) post-vaccination	

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	370	124		
Units: Subjects				
Any Pain	143	40		
Grade 3 Pain	7	1		
Any Redness	57	8		
Grade 3 Redness	1	0		
Any Swelling	42	4		
Grade 3 Swelling	1	0		

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 fatigue, fever [defined as oral temperature equal to or above 37.5 degrees Celsius (°C)], gastrointestinal and headache. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.5 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During the 4-day (Days 0-3) post-vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	371	125		
Units: Subjects				
Any Fatigue	55	13		
Grade 3 Fatigue	1	0		
Related Fatigue	35	8		
≥ 37.5 °C Fever	16	4		
>39.5 °C Fever	0	0		
Related Fever	10	2		
Any Gastrointestinal	13	5		
Grade 3 Gastrointestinal	2	0		
Related Gastrointestinal	6	0		
Any Headache	65	15		
Grade 3 Headache	3	0		
Related Headache	41	8		

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

End point type	Secondary

End point timeframe:

From Day 0 up to 6 Months after vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rash

End point title	Number of subjects with rash

End point description:

End point type	Secondary

End point timeframe:

From Day 0 up to 6 Months after vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with AEs resulting in emergency rooms visits

End point title	Number of subjects with AEs resulting in emergency rooms visits

End point description:

End point type	Secondary

End point timeframe:

From Day 0 up to 6 Months after vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects				
Any AE(s)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs

End point title	Number of subjects with unsolicited AEs

End point description:

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

End point type	Secondary

End point timeframe:

Up to 31 Days after vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects				
Any (AE)s	18	8		

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:

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 Day 0 up to 6 Months after vaccination

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	374	126		
Units: Subjects				
Any (SAE)s	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs

End point title	Number of subjects with SAEs

End point description:

SAEs assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

At Year 1, Year 2, Year 3, Year 4 and Year 5

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	364	121		
Units: Subjects				
Any (SAE)s Year 1	0	0		
Any (SAE)s Year 2	0	0		
Any (SAE)s Year 3	0	0		
Any (SAE)s Year 4	0	0		
Any (SAE)s Year 5	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Occurrence of solicited local and general symptoms during the 4-day (Days 0-3) post vaccination period;
Occurrence of unsolicited AE(s) up to 31 days after vaccination;
Occurrence of SAE(s) from Day 0 up to 6 months after vaccination.

Adverse event reporting additional description:

The solicited local and general symptoms were only collected for those subjects who filled in their symptom sheets. The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	Nimenrix Group

Reporting group description:

Subjects who received one dose of Nimenrix vaccine, administrated intramuscularly (IM) in the non-dominant deltoid region.

Reporting group title	Mencevax Group

Reporting group description:

Subjects who received one dose of Mencevax ACWY vaccine, administrated subcutaneous by injection into the non-dominant upper arm.

Serious adverse events	Nimenrix Group	Mencevax Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 374 (0.27%)	0 / 126 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Psychiatric disorders			
Mental disorder			
subjects affected / exposed	1 / 374 (0.27%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Costochondritis			
subjects affected / exposed	1 / 374 (0.27%)	0 / 126 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Nimenrix Group	Mencevax Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	143 / 374 (38.24%)	40 / 126 (31.75%)	
General disorders and administration site conditions			
Any Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	143 / 370 (38.65%)	40 / 124 (32.26%)	
occurrences (all)	143	40	
Any Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	57 / 370 (15.41%)	8 / 124 (6.45%)	
occurrences (all)	57	8	
Any Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	42 / 370 (11.35%)	4 / 124 (3.23%)	
occurrences (all)	42	4	
Any Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed[4]	55 / 371 (14.82%)	13 / 125 (10.40%)	
occurrences (all)	55	13	
Any Headache			
alternative assessment type: Systematic			
subjects affected / exposed[5]	65 / 371 (17.52%)	15 / 125 (12.00%)	
occurrences (all)	65	15	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 December 2011	Amendment 1 To support the data obtained by serum bactericidal assay (SBA) testing, antibody concentrations against meningococcal polysaccharides (PSs) were planned to be assessed by enzyme-linked immunosorbent assay (ELISA). The ELISA testing was performed prior to and one month after vaccination, and one, two and three years after vaccine administration, but the sponsor decided not to perform the ELISA testing at four and five years after vaccine administration for the following reasons: • the World Health Organisation (WHO) considers SBA the primary means of assessing immune response to meningococcal conjugate vaccines [WHO, 2006; WHO,1999]. • circulating bactericidal antibodies are more critical for persistent protection against meningococcal disease than non-functional antibodies against meningococcal PSs [Centers for Disease Control (CDC), 2011; WHO, 2006].

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported