Clinical trial results:
A phase III, randomized, open, controlled, multicenter primary vaccination study to demonstrate the non inferiority of the immunogenicity of meningococcal vaccine GSK134612 given intramuscularly versus Mencevax ACWY given subcutaneously to healthy subjects aged 11 through 17 years

Summary

EudraCT number	2012-000282-20
Trial protocol	Outside EU/EEA
Global end of trial date	10 September 2008

Results information

Result version number	v3 (current)
This version publication date	09 August 2022
First version publication date	06 March 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	109069

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00464815
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, 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)	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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 April 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 April 2008
Global end of trial reached?	Yes
Global end of trial date	10 September 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

One month after vaccination:
- To demonstrate the non-inferiority of the vaccine response induced by meningococcal vaccine GSK134612 compared to the licensed Mencevax ACWY measured by serum bactericidal antibodies using baby rabbit complement.
- To demonstrate the non-inferiority of meningococcal vaccine GSK 134612 compared to the licensed Mencevax ACWY in terms of the incidence of any grade 3 systemic symptom within four days after vaccination based on the analysis of pooled safety and reactogenicity data of this present study and study 109067 (MenACWY-TT-035).

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	02 May 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 392
Country: Number of subjects enrolled	Taiwan: 235
Country: Number of subjects enrolled	India: 398
Worldwide total number of subjects	1025
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)	172
Adolescents (12-17 years)	853
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:

The target sample size was 1024 enrolled subjects, but a total of 1025 subjects (in all age strata) were actually enrolled and vaccinated in seven study centres in India, Taiwan and the Philippines.

Period 1

Period 1 title	Overall (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Nimenrix (GSK134612) vaccine, administered intramuscularly into the deltoid region of the non-dominant arm.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	GSK134612
Other name	Meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose by intramuscular injection in the deltoid region of the non-dominant arm.

Arm title	Mencevax ACWY Group

Arm description:

Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Mencevax ACWY vaccine, administered subcutaneously into the non-dominant upper arm.

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

Dosage and administration details:

1 dose subcutaneously in the non-dominant upper arm.

Number of subjects in period 1	Nimenrix Group	Mencevax ACWY Group
Started	768	257
Completed	762	254
Not completed	6	3
Consent withdrawn by subject	6	3

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix Group
Reporting group description:	
Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Nimenrix (GSK134612) vaccine, administered intramuscularly into the deltoid region of the non-dominant arm.	
Reporting group title	Mencevax ACWY Group
Reporting group description:	
Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Mencevax ACWY vaccine, administered subcutaneously into the non-dominant upper arm.	

Reporting group values	Nimenrix Group	Mencevax ACWY Group	Total
Number of subjects	768	257	1025
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Healthy males and females aged 11 through 17 years who previously completed routine childhood immunizations to the best of parents'/guardians'knowledge and whose parents/guardians gave written informed consent. No previous vaccination with meningoccal polysaccharide vaccine of serogroups A, C, W-135 and/or Y within the last 5 years, or with meningococcal polysaccharide conjugate vaccine of serogroups A, C, W-135 and/or Y since birth. No previous vaccination with tetanus toxoid within the last month			
Units: years			
arithmetic mean	14.3	14.3	
standard deviation	± 1.97	± 1.97	-
Gender categorical			
Units: Subjects			
Female	414	135	549
Male	354	122	476

End points

End points reporting groups

Reporting group title	Nimenrix Group
Reporting group description:	
Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Nimenrix (GSK134612) vaccine, administered intramuscularly into the deltoid region of the non-dominant arm.	
Reporting group title	Mencevax ACWY Group
Reporting group description:	
Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Mencevax ACWY vaccine, administered subcutaneously into the non-dominant upper arm.	

Primary: Number of subjects with vaccine response to meningococcal antigens

End point title	Number of subjects with vaccine response to meningococcal antigens
End point description:	
Vaccine response induced by Neisseria meningitidis serogroups A, C, W-135 and Y (MenA, MenC, MenW-135 and menY) as measured by serum bactericidal antibodies using baby rabbit complement (rSBA), was defined as an rSBA titer of at least 1:32 in subjects initially seronegative [rSBA titer below (<) 1:8] and as a 4-fold increase in titer in subjects initially seropositive [rSBA titer greater than or equal to (≥) 1:8]. The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects for whom immunogenicity data were available.	
End point type	Primary
End point timeframe:	
One month after vaccination (At Month 1)	

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	657	219		
Units: Subjects				
rSBA-MenA (N=553,191,314,108)	472	148		
rSBA-MenC (N=642,211,365,119)	625	204		
rSBA-MenW-135 (N=639,216,362,125)	616	189		
rSBA-MenY (N=657,219,378,127)	616	172		

Statistical analyses

Statistical analysis title	Difference in % subjects with rSBA-MenA response
Statistical analysis description:	
To demonstrate the non-inferiority of Nimenrix vaccine versus Mencevax ACWY vaccine in term of rSBA-MenA vaccine response, the standardized asymptotic 95% CI for the difference in rSBA vaccine response rate for each of the meningococcal serogroup A (Nimenrix Group rate minus Mencevax ACWY Group rate) one month after vaccination was computed.	
Comparison groups	Nimenrix Group v Mencevax ACWY Group

Number of subjects included in analysis	876
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Rate difference
Point estimate	7.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.63
upper limit	14.87

Notes:

[1] - Criterion for non-inferiority: the lower limit of the 2-sided standardized asymptotic 95% confidence interval for the group difference (Nimenrig Group minus Mencevax ACWY Group) in the percentage of subjects with bactericidal vaccine response was greater than or equal to the pre-defined clinical limit of -10%

Statistical analysis title	Difference in % subjects with rSBA-MenC response

Statistical analysis description:

To demonstrate the non-inferiority of NImenriv vaccine versus Mencevax ACWY vaccine in term of rSBA-MenC vaccine response, the standardized asymptotic 95% CI for the difference in rSBA vaccine response rate for each of the meningococcal serogroup C (Nimenrix Group rate minus Mencevax ACWY Group rate) one month after vaccination was computed.

Comparison groups	Nimenrix Group v Mencevax ACWY Group
Number of subjects included in analysis	876
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Rates Difference
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.65
upper limit	4.18

Notes:

[2] - Criterion for non-inferiority: the lower limit of the 2-sided standardized asymptotic 95% confidence interval for the group difference [Nimenrix Group minus Mencevax ACWY Group] in the percentage of subjects with bactericidal vaccine response was greater than or equal to the pre-defined clinical limit of -10%

Statistical analysis title	Difference in % subjects with rSBA-MenW135response

Statistical analysis description:

To demonstrate the non-inferiority of Nimenrix vaccine versus Mencevax ACWY vaccine in term of rSBA-MenW-135 vaccine response, the standardized asymptotic 95% CI for the difference in rSBA vaccine response rate for each of the meningococcal serogroup W-135 (Nimenrix Group rate minus Mencevax ACWY Group rate) one month after vaccination was computed.

Comparison groups	Mencevax ACWY Group v Nimenrix Group
Number of subjects included in analysis	876
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Rate difference
Point estimate	8.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.78
upper limit	14.14

Notes:

[3] - Criterion for non-inferiority: the lower limit of the 2-sided standardized asymptotic 95% confidence interval for the group difference [Nimenrix Group minus Mencevax ACWY Group] in the percentage of subjects with bactericidal vaccine response was greater than or equal to the pre-defined clinical limit of -10%

Statistical analysis title	Difference in % subjects with rSBA-MenY response

Statistical analysis description:

To demonstrate the non-inferiority of Nimenrix vaccine versus Mencevax ACWY vaccine in term of rSBA-MenY vaccine response, the standardized asymptotic 95% CI for the difference in rSBA vaccine response rate for each of the meningococcal serogroup Y (Nimenrix Group rate minus Mencevax ACWY Group rate) one month after vaccination was computed.

Comparison groups	Nimenrix Group v Mencevax ACWY Group
Number of subjects included in analysis	876
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Rate difference
Point estimate	15.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.89
upper limit	21.37

Notes:

[4] - Criterion for non-inferiority: the lower limit of the 2-sided standardized asymptotic 95% confidence interval for the group difference [Nimenrix Group minus Mencevax ACWY Group] in the percentage of subjects with bactericidal vaccine response was greater than or equal to the pre-defined clinical limit of -10%

Primary: Number of subjects with any Grade 3 general (solicited and unsolicited) symptoms

End point title	Number of subjects with any Grade 3 general (solicited and unsolicited) symptoms

End point description:

General symptoms assessed included fatigue, fever (defined as axillary temperature), gastrointestinal symptoms and headache. Grade 3 symptom= event that prevented normal activities. Grade 3 fever= temperature above (>) 39.5 degrees Celsius (°C).
The analysis was performed on the Total Vaccinated cohort, which included all vaccinated subjects from whom data were available.

End point type	Primary

End point timeframe:

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

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	768	257		
Units: Subjects				
Subjects with Grade 3 symptoms	12	1		

Statistical analyses

Statistical analysis title	Ratio of % 109069 subjects with Grade 3 symptoms

Statistical analysis description:

To demonstrate the non-inferiority of Nimenrix vaccine versus Mencevax vaccine in term of incidence of any Grade 3 general (solicited and unsolicited) symptom, the 2-sided standardised asymptotic 95% CI for the ratio between Nimenrix and Mencevax groups (Nimenrix over Mencevax) in the percentage of subjects with any grade 3 general symptom within 4 days after vaccination was computed for the safety analysis in study MenACWY-TT-036.

Comparison groups	Nimenrix Group v Mencevax ACWY Group
Number of subjects included in analysis	1025
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
P-value	= 0.1456
Method	Chi-squared
Parameter estimate	Risk ratio (RR)
Point estimate	4.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	24.6

Notes:

[5] - Criterion for non-inferiority: the upper limit of the 2-sided standardized asymptotic 95% CI for the ratio of the percentages of subjects with any Grade 3 general symptom was lower than or equal to the pre-defined clinical limit of 3.0

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

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

End point description:

Neisseria meningitidis serogroups A, C, W-135 and Y were measured by serum bactericidal assay using baby rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY). The cut-off values for the rSBA titers was greater than or equal to (≥) 1:8 and ≥ 1:128.
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after vaccination (Month 1)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	678	224		
Units: Subjects				
rSBA-MenA, Month 0 ≥ 1:8 (N=557,191)	463	148		
rSBA-MenA, Month 0 ≥ 1:128 (N=557,191)	427	128		
rSBA-MenA, Month 1 ≥ 1:8 (N=674,224)	674	223		
rSBA-MenA, Month 1 ≥ 1:128 (N=674,224)	674	223		
rSBA-MenC, Month 0 ≥ 1:8 (N=648,211)	381	121		

rSBA-MenC, Month 0 ≥ 1:128 (N=648,211)	277	79		
rSBA-MenC, Month 1 ≥ 1:8 (N=673,224)	673	224		
rSBA-MenC, Month 1 ≥ 1:128 (N=673,224)	672	223		
rSBA- MenW-135, Month 0 ≥ 1:8 (N=640,216)	519	176		
rSBA- MenW-135, Month 0 ≥ 1:128 (N=640,216)	373	120		
rSBA- MenW-135, Month 1 ≥ 1:8 (N=678,224)	677	224		
rSBA- MenW-135, Month 1 ≥ 1:128 (N=678,224)	677	223		
rSBA-MenY, Month 0 ≥ 1:8 (N=659,219)	597	186		
rSBA-MenY, Month 0 ≥ 1:128 (N=659,219)	538	167		
rSBA-MenY, Month 1 ≥ 1:8 (N=677,224)	677	224		
rSBA-MenY, Month 1 ≥ 1:128 (N=677,224)	677	224		

Statistical analyses

No statistical analyses for this end point

Secondary: Meningococcal rSBA antibody titers

End point title	Meningococcal rSBA antibody titers

End point description:

rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers are presented as geometric mean titers (GMTs).
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after vaccination (Month 1)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	678	224		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, Month 0 (N=557,191,316,108)	208.1 (176.4 to 245.5)	155.9 (113.8 to 213.7)		
rSBA-MenA, Month 1 (N=674,224,388,128)	5928.5 (5557.4 to 6324.3)	2947.2 (2611.7 to 3325.7)		
rSBA-MenC, Month 0 (N=648,211,369,119)	44.1 (37.3 to 52.2)	40.9 (30.2 to 55.3)		

rSBA-MenC, Month 1 (N=673,224,387,128)	13109.8 (11939.1 to 14395.2)	8222 (6807.5 to 9930.4)		
rSBA- MenW-135, Month 0 (N=640,216,363,125)	109.4 (94.6 to 126.6)	112.2 (87.2 to 144.3)		
rSBA- MenW-135, Month 1 (N=678,224,390,128)	8246.6 (7638.8 to 8902.7)	2632.7 (2299.3 to 3014.4)		
rSBA-MenY, Month 0 (N=659,219,380,127)	348.3 (303.5 to 399.7)	299 (225.2 to 397)		
rSBA-MenY, Month 1 (N=677,224,389,128)	14086.5 (13168 to 15069)	5066.3 (4463.1 to 5750.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-tetanus toxoid (Anti-TT) greater than (>) the cut-off value

End point title	Number of subjects with anti-tetanus toxoid (Anti-TT) greater than (>) the cut-off value

End point description:

The cut-off value of the assay was an anti-tetanus toxoid antibody titer greater than (>) 0.1 international units per milliliter (IU/mL).
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after vaccination (Month 1)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	679	224		
Units: Subjects				
Anti-TT, Month 0 (N=679,224,391,128)	439	155		
Anti-TT, Month 1 (N=679,224,391,128)	662	157		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-TT antibody concentrations

End point title	Anti-TT antibody concentrations

End point description:

Antibody concentrations are presented as geometric mean concentrations (GMCs) and expressed in

international units per milliliter (IU/mL).
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month (Month 1) after vaccination

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	679	224		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-TT, Month 0 (N=679,224,391,128)	0.367 (0.321 to 0.419)	0.41 (0.326 to 0.516)		
Anti-TT, Month 1 (N=679,224,391,128)	10.305 (9.131 to 11.631)	0.459 (0.364 to 0.58)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-meningococcal polysaccharides (PS) antibody concentrations ≥ the cut-off values

End point title	Number of subjects with anti-meningococcal polysaccharides (PS) antibody concentrations ≥ the cut-off values

End point description:

The cut-off values of the assay was an anti-PS concentration greater than or equal to (≥) 0.3 micrograms per milliliter (µg/mL) and ≥ 2.0 µg/mL.
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month after vaccination (Month 1)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	347	114		
Units: Subjects				
Anti-PSA ≥ 0.3 ug/mL, Month 0 (N=322,102,189,59)	235	75		
Anti-PSA ≥ 0.3 ug/mL, Month 1 (N=341,107,194,59)	341	107		
Anti-PSC ≥ 0.3 ug/mL, Month 0 (N=335,108,190,60)	50	21		

Anti-PSC ≥ 0.3 ug/mL, Month 1 (N=331,107,188,60)	331	107		
Anti-PSW-135 ≥0.3 ug/mL,Month 0 (N=340,111,204,64)	40	8		
Anti-PSW-135 ≥0.3ug/mL, Month 1 (N=344,114,205,66)	340	113		
Anti-PSY ≥ 0.3 ug/mL, Month 0 (N=347,114,206,68)	49	16		
Anti-PSY ≥ 0.3 ug/mL, Month 1 (N=342,114,201,66)	342	113		
Anti-PSA ≥ 2 ug/mL, Month 0 (N=322,102,189,59)	130	40		
Anti-PSA ≥ 2 ug/mL, Month 1 (N=341,107,194,59)	341	107		
Anti-PSC ≥ 2 ug/mL, Month 0 (N=335,108,190,60)	17	10		
Anti-PSC ≥ 2 ug/mL, Month 1 (N=331,107,188,60)	324	106		
Anti-PSW-135 ≥ 2 ug/mL, Month 0 (N=340,111,204,64)	9	3		
Anti-PSW-135 ≥ 2 ug/mL, Month 1 (N=344,114,205,66)	327	106		
Anti-PSY ≥ 2 ug/mL, Month 0 (N=347,114,206,68)	12	8		
Anti-PSY ≥ 2 ug/mL, Month 1 (N=342,114,201,66)	336	111		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-meningococcal polysaccharide concentrations

End point title	Anti-meningococcal polysaccharide concentrations

End point description:

Antibody concentrations were presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL).
The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects for whom data concerning immunogenicity outcome variable measures and assay results were available for antibodies against at least one study vaccine antigen component.

End point type	Secondary

End point timeframe:

Prior to (Month 0) and one month (Month 1) after vaccination

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	347	114		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, Month 0 (N=322,102,189,59)	1.05 (0.88 to 1.24)	1.04 (0.77 to 1.39)		

Anti-PSA, Month 1 (N=341,107,194,59)	86.06 (75.35 to 98.29)	44.06 (34.4 to 56.42)		
Anti-PSC, Month 0 (N=335,108,190,60)	0.21 (0.19 to 0.24)	0.25 (0.2 to 0.3)		
Anti-PSC, Month 1 (N=331,107,188,60)	22.83 (20.42 to 25.52)	43.24 (35.8 to 52.23)		
Anti-PSW-135, Month 0 (N=340,111,204,64)	0.18 (0.17 to 0.2)	0.18 (0.16 to 0.21)		
Anti-PSW-135, Month 1 (N=344,114,205,66)	17.82 (15.34 to 20.7)	13.22 (10.47 to 16.68)		
Anti-PSY, Month 0 (N=347,114,206,68)	0.2 (0.18 to 0.22)	0.22 (0.18 to 0.28)		
Anti-PSY, Month 1 (N=342,114,201,66)	23.77 (20.95 to 26.98)	17.97 (14.3 to 22.59)		

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:

Solicited local symptoms assessed included pain, redness and swelling. Any= incidence of a particular symptom regardless of intensity. Grade 3 symptoms= symptoms that prevented normal activity. Grade 3 swelling= swelling spreading beyond 50 millimeters (mm).
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects who had the symptoms sheet filled in.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0 to Day 3) period after vaccination

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	763	254		
Units: Subjects				
Any Pain	200	68		
Grade 3 Pain	6	0		
Any Redness	94	16		
Grade 3 Redness	2	0		
Any Swelling	71	16		
Grade 3 Swelling	9	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:

Solicited general symptoms assessed included fatigue, fever [defined as axillary temperature equal to or above (≥) 37.5 degrees Celsius (°C)]. Any= incidence of a particular symptom regardless of intensity or relationship to vaccination. Grade 3= event that prevented normal activities. Grade 3 fever= fever > 39.5 °C. Related= general symptom assessed by the investigator as causally related to the study vaccination.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects who had the symptoms sheet filled in.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0 to Day 3) period after vaccination

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	763	254		
Units: Subjects				
Any Fatigue	109	36		
Grade 3 Fatigue	7	1		
Related Fatigue	83	26		
Any Fever (Axillary)	55	13		
Grade 3 Fever	3	0		
Related Fever	42	10		
Any Gastrointestinal symptoms	35	11		
Grade 3 Gastrointestinal symptoms	0	1		
Related Gastrointestinal symptoms	24	9		
Any Headache	102	27		
Grade 3 Headache	5	1		
Related Headache	81	19		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited adverse events

End point title	Number of subjects with any unsolicited adverse events

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.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	768	257		
Units: Subjects				
Any AEs	72	26		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any serious adverse events (SAEs)

End point title	Number of subjects with any 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.
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

Up to study end (Month 6)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	768	257		
Units: Subjects				
Any SAEs	3	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with specific adverse events

End point title	Number of subjects with specific adverse events

End point description:

These events included the specific categories of adverse events (AEs) which included rash (e.g. hives, idiopathic thrombocytopenia purpura, petechiae), new onset of chronic illness(es) (NOCIs) (e.g. autoimmune disorders, asthma, type I diabetes and allergies), conditions prompting emergency room (ER) visits or non-routine physician office visits (i.e. office visits not related to well-being care, vaccination, injury or common acute illnesses such as upper respiratory tract infections, otitis media, pharyngitis, gastroenteritis), any events related to lack of meningococcal vaccine efficacy (i.e. meningococcal disease).
The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

Up to study end (Month 6)

End point values	Nimenrix Group	Mencevax ACWY Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	768	257		
Units: Subjects				
Any Rash	6	1		
Any NOCIs	0	0		
Any ER visits	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general adverse events (AEs): during the 4-day (Days 0-3) period after vaccination. Unsolicited AEs: up to one month after vaccination (Month 1). SAEs and specific AEs: up to study end (Month 6).

Adverse event reporting additional description:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	12.0

Reporting groups

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Nimenrix (GSK134612) vaccine, administered intramuscularly into the deltoid region of the non-dominant arm.

Reporting group title	Mencevax ACWY Group

Reporting group description:

Healthy male and female subjects aged 11 through 17 years, who received 1 dose of Mencevax ACWY vaccine, administered subcutaneously into the non-dominant upper arm.

Serious adverse events	Nimenrix Group	Mencevax ACWY Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 768 (0.39%)	2 / 257 (0.78%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Humerus fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 768 (0.00%)	1 / 257 (0.39%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Peptic ulcer			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 768 (0.26%)	0 / 257 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Amoebic dysentery			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 768 (0.13%)	0 / 257 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 768 (0.00%)	1 / 257 (0.39%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritoneal abscess			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 768 (0.00%)	1 / 257 (0.39%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 768 (0.13%)	0 / 257 (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 ACWY Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	311 / 768 (40.49%)	99 / 257 (38.52%)	
General disorders and administration site conditions			
Pain			
subjects affected / exposed	200 / 768 (26.04%)	68 / 257 (26.46%)	
occurrences (all)	200	68	
Redness			
subjects affected / exposed	94 / 768 (12.24%)	16 / 257 (6.23%)	
occurrences (all)	94	16	

Swelling			
subjects affected / exposed	71 / 768 (9.24%)	16 / 257 (6.23%)	
occurrences (all)	71	16	
Fatigue			
subjects affected / exposed	109 / 768 (14.19%)	36 / 257 (14.01%)	
occurrences (all)	109	36	
Fever			
subjects affected / exposed	55 / 768 (7.16%)	13 / 257 (5.06%)	
occurrences (all)	55	13	
Headache			
subjects affected / exposed	102 / 768 (13.28%)	27 / 257 (10.51%)	
occurrences (all)	102	27	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported