Clinical trial results:
A phase III, open, controlled study to assess the persistence of antibodies after one dose of GlaxoSmithKline Biologicals' meningococcal serogroup ACWY conjugate vaccine (MenACWY-TT) given intramuscularly versus one dose of Mencevax™ ACWY given subcutaneously to healthy subjects aged 11 through 17 years in the primary study 109069 (MenACWY-TT-036)

Summary

EudraCT number	2012-005641-21
Trial protocol	Outside EU/EEA
Global end of trial date	17 May 2013

Results information

Result version number	v1
This version publication date	10 March 2016
First version publication date	17 July 2015

Trial information

Trial identification

Sponsor protocol code	112148

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00974363
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	20 June 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 May 2013
Global end of trial reached?	Yes
Global end of trial date	17 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

At 24, 36, 48, and 60 months after primary vaccination of adolescents with MenACWY-TT or Mencevax™ ACWY vaccine, to evaluate the persistence of meningococcal antibodies in terms of percentage of subjects with rSBA titres ≥ 8 for each of the four serogroups.

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	08 September 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 388
Country: Number of subjects enrolled	India: 309
Worldwide total number of subjects	697
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)	0
Adolescents (12-17 years)	697
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.

Pre-assignment period milestones

Number of subjects started	697
Number of subjects completed	689

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No vaccination received: 8

Period 1

Period 1 title	Overall Study (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:

Subjects vaccinated with a single dose of MenACWY-TT vaccine.

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

Dosage and administration details:

MenACWY-TT vaccine was administered by intramuscular injection in the deltoid region of the non-dominant arm.

Arm title	Mencevax Group

Arm description:

Subjects vaccinated with a single dose of MenACWY vaccine.

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

Dosage and administration details:

MenACWY vaccine was administered subcutaneously in the non-dominant upper arm.

Number of subjects in period 1[1]	Nimenrix Group	Mencevax Group
Started	521	168
Completed	521	168

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 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 vaccinated with a single dose of MenACWY-TT vaccine.	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY vaccine.	

Reporting group values	Nimenrix Group	Mencevax Group	Total
Number of subjects	521	168	689
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	16.4	16.4	
standard deviation	± 1.94	± 2	-
Gender categorical			
Units: Subjects			
Female	273	86	359
Male	248	82	330

End points

End points reporting groups

Reporting group title	Nimenrix Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY-TT vaccine.	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY vaccine.	

Primary: Number of subjects with rSBA-MenA antibody titres ≥1:8.

End point title	Number of subjects with rSBA-MenA antibody titres ≥1:8.[1]
End point description:	
These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.	
End point type	Primary
End point timeframe:	
At months 24, 36 and 48 post primary dose.	

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.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenA Month 24 GSK laboratory [N=445;144]	444	144		
rSBA-MenA Month 36 GSK laboratory [N=465;149]	465	149		
rSBA-MenA Month 36 HPA laboratory [N=472;154]	440	128		
rSBA-MenA Month 48 GSK laboratory [N=399;130]	399	130		
rSBA-MenA Month 48 HPA laboratory [N=403;133]	363	107		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenC antibody titres ≥1:8.

End point title	Number of subjects with rSBA-MenC antibody titres ≥1:8.[2]
End point description:	
These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.	

End point type	Primary

End point timeframe:

At months 24, 36 and 48 post primary dose.

Notes:

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

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenC Month 24 GSK laboratory [N=447;145]	444	143		
rSBA-MenC Month 36 GSK laboratory [N=468;150]	465	149		
rSBA-MenC Month 36 HPA laboratory [N=472;154]	432	133		
rSBA-MenC Month 48 GSK laboratory [N=401;130]	398	128		
rSBA-MenC Month 48 HPA laboratory [N=402;133]	379	116		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenW-135 antibody titres ≥1:8.

End point title	Number of subjects with rSBA-MenW-135 antibody titres

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Primary

End point timeframe:

At months 24, 36 and 48 post primary dose.

Notes:

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

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenW-135 Month 24 GSK laboratory [N=447;143]	445	136		
rSBA-MenW-135 Month 36 GSK laboratory [N=468;147]	467	140		
rSBA-MenW-135 Month 36 HPA laboratory [N=472;154]	389	47		

rSBA-MenW-135 Month 48 GSK laboratory [N=401;129]	400	122		
rSBA-MenW-135 Month 48 HPA laboratory [N=402;132]	311	36		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenY antibody titres ≥1:8.

End point title	Number of subjects with rSBA-MenY antibody titres ≥1:8.[4]

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Primary

End point timeframe:

At months 24, 36 and 48 post primary dose.

Notes:

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

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenY Month 24 GSK laboratory [N=447;142]	447	138		
rSBA-MenY Month 36 GSK laboratory [N=468;147]	468	143		
rSBA-MenY Month 36 HPA laboratory [N=472;154]	441	89		
rSBA-MenY Month 48 GSK laboratory [N=401;128]	401	124		
rSBA-MenY Month 48 HPA laboratory [N=400;132]	358	64		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA antibody titres ≥1:128.

End point title	Number of subjects with rSBA-MenA antibody titres ≥1:128.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenA Month 24 GSK laboratory [N=445;144]	443	140		
rSBA-MenA Month 36 GSK laboratory [N=465;149]	464	145		
rSBA-MenA Month 36 HPA laboratory [N=472;154]	421	122		
rSBA-MenA Month 48 GSK laboratory [N=399;130]	398	126		
rSBA-MenA Month 48 HPA laboratory [N=403;133]	344	101		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenC antibody titres ≥1:128.

End point title	Number of subjects with rSBA-MenC antibody titres ≥1:128.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenC Month 24 GSK laboratory [N=447;145]	434	137		
rSBA-MenC Month 36 GSK laboratory [N=468;150]	452	143		
rSBA-MenC Month 36 HPA laboratory [N=472;154]	401	121		
rSBA-MenC Month 48 GSK laboratory [N=401;130]	387	122		
rSBA-MenC Month 48 HPA laboratory [N=402;133]	359	107		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenW-135 antibody titres ≥1:128.

End point title	Number of subjects with rSBA-MenW-135 antibody titres ≥1:128.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenW-135 Month 24 GSK laboratory [N=447;143]	443	124		
rSBA-MenW-135 Month 36 GSK laboratory [N=468;147]	465	129		
rSBA-MenW-135 Month 36 HPA laboratory [N=472;154]	371	38		
rSBA-MenW-135 Month 48 GSK laboratory [N=401;129]	398	111		
rSBA-MenW-135 Month 48 HPA laboratory [N=402;132]	292	26		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenY antibody titres ≥1:128.

End point title	Number of subjects with rSBA-MenY antibody titres ≥1:128.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Subjects				
rSBA-MenY Month 24 GSK laboratory [N=447;142]	447	135		
rSBA-MenY Month 36 GSK laboratory [N=468;147]	468	140		
rSBA-MenY Month 36 HPA laboratory [N=472;154]	422	79		
rSBA-MenY Month 48 GSK laboratory [N=401;128]	401	121		
rSBA-MenY Month 48 HPA laboratory [N=400;132]	343	61		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA.

End point title	Antibody titers for rSBA-MenA.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA Month 24 GSK laboratory [N=445;144]	1517.4 (1399.7 to 1645.1)	810.6 (695.9 to 944.3)		
rSBA-MenA Month 36 GSK laboratory [N=465;149]	1531.6 (1421.7 to 1650)	821.9 (710.5 to 950.9)		
rSBA-MenA Month 36 HPA laboratory [N=472;154]	470.2 (402.1 to 549.8)	211.9 (152.7 to 294.1)		
rSBA-MenA Month 48 GSK laboratory [N=399;130]	1484.8 (1370 to 1609.3)	756.9 (652.3 to 878.2)		
rSBA-MenA Month 48 HPA laboratory [N=403;133]	375.7 (312.4 to 451.7)	171.4 (119.6 to 245.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenC.

End point title	Antibody titers for rSBA-MenC.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC Month 24 GSK laboratory [N=447;145]	1121.9 (996.9 to 1262.6)	1499 (1119.6 to 2006.8)		
rSBA-MenC Month 36 GSK laboratory [N=468;150]	1111.2 (990.4 to 1246.6)	1577.2 (1204.1 to 2065.8)		
rSBA-MenC Month 36 HPA laboratory [N=472;154]	375.6 (314.8 to 448.1)	407 (275.7 to 600.8)		
rSBA-MenC Month 48 GSK laboratory [N=401;130]	1063.6 (940.2 to 1203.2)	1316.9 (970.9 to 1786.1)		
rSBA-MenC Month 48 HPA laboratory [N=402;133]	376.7 (319.6 to 444)	368.7 (248 to 548.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenW-135.

End point title	Antibody titers for rSBA-MenW-135.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenW-135 Month 24 GSK laboratory [N=447;143]	2070.6 (1869.8 to 2293)	442.6 (341.8 to 573)		
rSBA-MenW-135 Month 36 GSK laboratory [N=468;147]	2091.8 (1899.7 to 2303.4)	443.2 (344.9 to 569.5)		
rSBA-MenW-135 Month 36 HPA laboratory [N=472;154]	352.6 (282 to 440.9)	16.4 (11.2 to 24.1)		
rSBA-MenW-135 Month 48 GSK laboratory [N=401;129]	1999.5 (1802.4 to 2218.1)	393.5 (301.2 to 514.1)		
rSBA-MenW-135 Month 48 HPA laboratory [N=402;132]	208.2 (163.3 to 265.3)	12 (8.4 to 17.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenY.

End point title	Antibody titers for rSBA-MenY.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At months 24, 36 and 48 post primary dose.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	472	154		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenY Month 24 GSK laboratory [N=447;142]	3715.9 (3409.3 to 4049.9)	1090.3 (857.7 to 1386.1)		

rSBA-MenY Month 36 GSK laboratory [N=468;147]	3701.8 (3401.9 to 4028)	1122.4 (886.4 to 1421.3)		
rSBA-MenY Month 36 HPA laboratory [N=472;154]	752.3 (633.3 to 893.6)	68.5 (44.2 to 106.1)		
rSBA-MenY Month 48 GSK laboratory [N=401;128]	3406.2 (3114.9 to 3724.7)	999 (780.8 to 1278.2)		
rSBA-MenY Month 48 HPA laboratory [N=400;132]	545 (440.7 to 673.9)	49.5 (30.6 to 79.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide A (anti-PSA), anti-polysaccharide C (anti-PSC), anti-polysaccharide W-135 (anti-PSW-135) and anti-polysaccharide Y (anti-PSY) antibody concentrations equal to or above the cut-off values.

End point title	Number of subjects with anti-polysaccharide A (anti-PSA), anti-polysaccharide C (anti-PSC), anti-polysaccharide W-135 (anti-PSW-135) and anti-polysaccharide Y (anti-PSY) antibody concentrations equal to or above the cut-off values.

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory and by GSK Biologicals' laboratory.

End point type	Secondary

End point timeframe:

At month 24.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226	73		
Units: Subjects				
Anti-PSA ≥ 0.3 µg/mL [N=217;72]	217	72		
Anti-PSA ≥ 2.0 µg/mL [N=217;72]	199	71		
Anti-PSC ≥ 0.3 µg/mL [N=212;73]	195	73		
Anti-PSC ≥ 2.0 µg/mL [N=212;73]	103	68		
Anti-PSW-135 ≥ 0.3 µg/mL [N=216;68]	204	67		
Anti-PSW-135 ≥ 2.0 µg/mL [N=216;68]	135	54		
Anti-PSY ≥ 0.3 µg/mL [N=226;71]	220	69		
Anti-PSY ≥ 2.0 µg/mL [N=226;71]	140	56		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibodies.

End point title	Concentrations of anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibodies.

End point description:

End point type	Secondary

End point timeframe:

At month 24.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226	73		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PSA [N=217;72]	10.68 (8.97 to 12.72)	18.47 (13.79 to 24.74)		
Anti-PSC [N=212;73]	1.96 (1.63 to 2.34)	10.76 (8.25 to 14.02)		
Anti-PSW-135 [N=216;68]	3.15 (2.62 to 3.79)	5.51 (4.01 to 7.58)		
Anti-PSY [N=226;71]	3.51 (2.93 to 4.21)	7.37 (5.2 to 10.45)		

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:

End point type	Secondary

End point timeframe:

At months 24, 36 and 48.

End point values	Nimenrix Group	Mencevax Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	521	168		
Units: Subjects				
SAEs Month 24 [N=521;168]	0	0		
SAEs Month 36 [N=488;155]	0	0		
SAEs Month 48 [N=407;134]	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
Serious adverse events (SAEs): up to Month 24, 36 an 48.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.1

Reporting groups	
Reporting group title	Nimenrix Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY-TT vaccine.	
Reporting group title	Mencevax Group
Reporting group description:	
Subjects vaccinated with a single dose of MenACWY vaccine.	

Serious adverse events	Nimenrix Group	Mencevax Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 521 (0.00%)	0 / 168 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	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	0 / 521 (0.00%)	0 / 168 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No information about unsolicited AEs was collected during this study as no product was administered.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 December 2011	The primary objective of the study was to evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rabbit serum bactericidal assay (rSBA) titres ≥1:8 for each of the four serogroups (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) at 24, 36, 48 and 60 months after primary vaccination of adolescents with MenACWY-TT or Mencevax™ ACWY vaccine. To support the data obtained by rSBA testing, antibody concentrations against meningococcal polysaccharides are planned to be assessed by ELISA (anti-polysaccharides [PS] testing) at 24, 36, 48 and 60 months after primary vaccination with MenACWY-TT. The anti-PS testing will be performed at 24 months after vaccine administration, but the sponsor decided not to perform the anti-PS testing at 36, 48 and 60 months 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 polysaccharides [Centres for Disease Control (CDC), 2011; WHO, 2006]. Although antibody concentrations will not be determined by ELISA at 36, 48 and 60 months after primary vaccination with MenACWY-TT or, all subjects will be informed of their rSBA antibody titres at each immunogenicity time point when statistical analyses at that time point have been completed. In addition: •The protocol amendment clarifies in which laboratory the different assays will be performed. •The introduction has been updated with the current licensing status of competitor vaccines and the current recommendations for meningococcal vaccines. The rationale for the study has been updated according to this new information. •The list of abbreviations and reference list have been updated according to changes in the clinical study team.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported