Clinical trial results:
Persistence of antibodies after vaccination with a dose of GSK Biologicals' meningococcal vaccine GSK134612 in healthy children and safety and immunogenicity of a booster dose at 68 months post-primary vaccination.

Summary

EudraCT number	2010-018730-51
Trial protocol	FR DE
Global end of trial date	17 May 2014
Results information	
Result version number	v2
This version publication date	21 April 2016
First version publication date	24 May 2015
Version creation reason	• New data added to full data set Data for Month 56, 68 and 69 have been added.

Trial information

Trial identification	
Sponsor protocol code	113977
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01266993
WHO universal trial number (UTN)	-

Notes:

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

Notes:

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2014
Global end of trial reached?	Yes
Global end of trial date	17 May 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Persistence
At 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or MenC-CRM.
•To evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rSBAMenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY titres ≥1:8.

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 January 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	37 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 97
Country: Number of subjects enrolled	Germany: 185
Worldwide total number of subjects	282
EEA total number of subjects	282

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)	282

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

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

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

Pre-assignment period milestones

Number of subjects started	282
Number of subjects completed	271

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No vaccination received: 11

Period 1

Period 1 title	Month 32
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Month 32 Group

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Arm title	Menjugate Month 32 Group

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Number of subjects in period 1[1]	Nimenrix Month 32 Group	Menjugate Month 32 Group
Started	199	72
Completed	199	72

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 subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

Period 2

Period 2 title	Month 44
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Month 44 Group

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Arm title	Menjugate Month 44 Group

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Number of subjects in period 2[2]	Nimenrix Month 44 Group	Menjugate Month 44 Group
Started	193	68
Completed	193	68

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 subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

Period 3

Period 3 title	Month 56
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Month 56 Group

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study and a booster dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Arm title	Menjugate Month 56 Group

Arm description:

Subjects who received Menjugate® in the primary study and a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Number of subjects in period 3[3]	Nimenrix Month 56 Group	Menjugate Month 56 Group
Started	193	67
Completed	193	67

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 subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

Period 4

Period 4 title	Month 68
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Month 68 Group

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Arm title	Menjugate Month 68 Group

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Number of subjects in period 4[4]	Nimenrix Month 68 Group	Menjugate Month 68 Group
Started	179	62
Completed	179	62

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 subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

Period 5

Period 5 title	Month 69 (Booster)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Month 69 Group

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Arm title	Menjugate Month 69 Group

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

Arm type	Experimental
Investigational medicinal product name	Nimerix™
Investigational medicinal product code	
Other name	GSK134612 vaccine MenACWY-TT
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

Number of subjects in period 5	Nimenrix Month 69 Group	Menjugate Month 69 Group
Started	179	62
Completed	174	60
Not completed	5	2
Consent withdrawn by subject	-	1
Lost to follow-up	5	1

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix Month 32 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 32 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.	

Reporting group values	Nimenrix Month 32 Group	Menjugate Month 32 Group	Total
Number of subjects	199	72	271
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	8.4	8.1	
standard deviation	± 2.58	± 2.42	-
Gender categorical			
Units: Subjects			
Female	103	34	137
Male	96	38	134

End points

End points reporting groups

Reporting group title	Nimenrix Month 32 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 32 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.	
Reporting group title	Nimenrix Month 44 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 44 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study	
Reporting group title	Nimenrix Month 56 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study and a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 56 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study and a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study	
Reporting group title	Nimenrix Month 68 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 68 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.	
Reporting group title	Nimenrix Month 69 Group
Reporting group description:	
Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.	
Reporting group title	Menjugate Month 69 Group
Reporting group description:	
Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.	

Primary: Number of subjects with serum bactericidal assay against Neisseria meningitides serogroup A, C, W-135, Y, using baby rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) antibody titres ≥1:8

End point title	Number of subjects with serum bactericidal assay against Neisseria meningitides serogroup A, C, W-135, Y, using baby rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) antibody titres ≥1:8[1]
End point description:	
These analyses were performed by the Health Protection Agency (HPA) laboratory	

End point type	Primary

End point timeframe:

At month 32 after primary vaccination

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 Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	69		
Units: Subjects				
rSBA-MenA [N=193;69]	167	15		
rSBA-MenC [N=192;69]	124	53		
rSBA-MenW-135 [N=193;69]	149	5		
rSBA-MenY [N=193;69]	157	10		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[2]

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Primary

End point timeframe:

At month 44 after primary vaccination

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 Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	66		
Units: Subjects				
rSBA-MenA [N=189;66]	162	17		
rSBA-MenC [N=189;66]	70	30		
rSBA-MenW-135 [N=189;66]	129	7		
rSBA-MenY [N=189;66]	118	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[3]

End point description:

These analyses were performed by the GSK laboratory

End point type	Primary

End point timeframe:

At 32 months after the primary vaccination

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 Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	192	67		
Units: Subjects				
rSBA-MenA [N=191;57]	191	25		
rSBA-MenC [N=189;67]	189	67		
rSBA-MenW-135 [N=192;65]	192	52		
rSBA-MenY [N=191;65]	191	51		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[4]

End point description:

These analyses were performed by the GSK laboratory

End point type	Primary

End point timeframe:

At 44 months after the primary vaccination

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 Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	64		
Units: Subjects				
rSBA-MenA [N=187;55]	187	24		
rSBA-MenC [N=186;64]	186	64		
rSBA-MenW-135 [N=188;62]	188	49		
rSBA-MenY [N=187;62]	187	49		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[5]

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Primary

End point timeframe:

At 56 months after the primary vaccination

Notes:

[5] - 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 Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	65		
Units: Subjects				
rSBA-MenA [N=186;65]	161	19		
rSBA-MenC [N=186;65]	110	42		
rSBA-MenW-135 [N=186;65]	145	17		
rSBA-MenY [N=186;64]	149	14		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[6]

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Primary

End point timeframe:

At 68 months after the primary vaccination

Notes:

[6] - 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 Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Subjects				
rSBA-MenA [N=178;61]	154	18		
rSBA-MenC [N=178;61]	71	38		
rSBA-MenW-135 [N=178;61]	94	9		
rSBA-MenY [N=178;61]	127	8		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[7]

End point description:

These analyses were performed by the GSK laboratory .

End point type	Primary

End point timeframe:

At 56 months after the primary vaccination

Notes:

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

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	185	63		
Units: Subjects				
rSBA-MenA [N=184;54]	184	24		
rSBA-MenC [N=182;63]	182	63		
rSBA-MenW-135 [N=185;61]	185	48		
rSBA-MenY [N=184;61]	184	49		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:8[8]

End point description:

These analyses were performed by the GSK laboratory

End point type	Primary

End point timeframe:

At 68 months after the primary vaccination

Notes:

[8] - 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 Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	59		
Units: Subjects				
rSBA-MenA [N=176;51]	176	24		
rSBA-MenC [N=174;59]	174	59		
rSBA-MenW-135 [N=177;58]	177	46		
rSBA-MenY [N=176;57]	176	47		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 32 months after the primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	69		
Units: Subjects				
rSBA-MenA [N=193;69]	140	9		
rSBA-MenC [N=192;69]	69	35		
rSBA-MenW-135 [N=193;69]	136	5		
rSBA-MenY [N=193;69]	145	8		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 44 months after the primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	66		
Units: Subject				
rSBA-MenA [N=189;66]	151	16		
rSBA-MenC [N=189;66]	38	23		
rSBA-MenW-135 [N=189;66]	120	5		
rSBA-MenY [N=189;66]	107	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 32 months after the primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	192	67		
Units: Subjects				
rSBA-MenA [N=191;57]	191	19		
rSBA-MenC [N=189;67]	186	67		
rSBA-MenW-135 [N=192;65]	191	30		
rSBA-MenY [N=191;65]	191	34		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 44 months after the primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	64		
Units: Subjects				
rSBA-MenA [N=187;55]	187	18		
rSBA-MenC [N=186;64]	183	64		
rSBA-MenW-135 [N=188;62]	187	29		
rSBA-MenY [N=187;62]	187	32		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 32 months after the primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	69		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=193;69]	196.3 (144.1 to 267.2)	8 (5.5 to 11.7)		
rSBA-MenC [N=192;69]	34.8 (26 to 46.4)	86.5 (47.3 to 158.1)		
rSBA-MenW-135 [193;69]	213.9 (149.3 to 306.6)	5.6 (4.2 to 7.6)		
rSBA-MenY [N=193;69]	227.4 (164.8 to 313.7)	7.2 (5 to 10.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 44 months after the primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	66		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=189;66]	307.5 (223.7 to 422.8)	13.5 (8 to 23)		
rSBA-MenC [N=189;66]	14.5 (10.9 to 19.2)	31 (16.6 to 58)		
rSBA-MenW-135 [N=189;66]	103.5 (72.5 to 147.6)	5.9 (4.3 to 8.1)		
rSBA-MenY [N=189;66]	78.9 (54.6 to 114)	4.9 (3.9 to 6.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 32 months after the primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	192	67		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=191;57]	6733.3 (5927 to 7649.3)	27.2 (14.4 to 51.1)		
rSBA-MenC [N=189;67]	2588 (2124.5 to 3152.7)	5135.3 (3436.5 to 7674.1)		

rSBA-MenW-135 [N=192;65]	8959.1 (7828.9 to 10252.5)	77.9 (49.4 to 122.9)		
rSBA-MenY [N=191;65]	8543.9 (7405 to 9858.1)	86.5 (54.5 to 137.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 44 months after the primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	64		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=187;55]	6633.2 (5830.3 to 7546.6)	26.9 (14.1 to 51.3)		
rSBA-MenC [N=186;64]	2609 (2134.9 to 3188.3)	5120.1 (3432 to 7638.4)		
rSBA-MenW-135 [N=188;62]	9158.4 (7975 to 10517.4)	76.9 (47.9 to 123.6)		
rSBA-MenY [N=187;62]	8520.4 (7362.2 to 9860.8)	87.2 (54.4 to 139.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay against N. meningitides serogroup A, C, W-135, Y, using human complement (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titres ≥1:4

End point title	Number of subjects with serum bactericidal assay against N.

	meningitides serogroup A, C, W-135, Y, using human complement (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titres ≥1:4

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 32 after primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	34		
Units: Subjects				
hSBA-MenA [N=90;34]	24	5		
hSBA-MenC [N=90;33]	86	30		
hSBA-MenW-135 [N=86;23]	73	4		
hSBA-MenY [N=91;28]	74	13		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 44 after primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Subjects				
hSBA-MenA [N=89;31]	26	5		
hSBA-MenC [N=82;31]	63	20		
hSBA-MenW-135 [N=87;30]	70	8		
hSBA-MenY [N=76;26]	63	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 32 after primary vaccination

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	34		
Units: Subjects				
hSBA-MenA [N=90;34]	23	5		
hSBA-MenC [N=90;33]	86	30		
hSBA-MenW-135 [N=86;23]	73	4		
hSBA-MenY [N=91;28]	74	13		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 44 after primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Subjects				
hSBA-MenA [N=89;31]	23	5		
hSBA-MenC [N=82;31]	63	20		
hSBA-MenW-135 [N=87;30]	70	8		
hSBA-MenY [N=76;26]	63	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens
End point description:	
This analysis was performed on 50% of the subjects in each group	
End point type	Secondary
End point timeframe:	
At Month 32 after primary vaccination	

End point values	Nimenrix Month 32 Group	Menjugate Month 32 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	34		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=90;34]	4.6 (3.3 to 6.3)	2.7 (2.1 to 3.4)		
hSBA-MenC [N=90;33]	75.9 (53.4 to 107.9)	82.2 (34.6 to 195.8)		
hSBA-MenW-135 [N=86;23]	69.9 (48.2 to 101.5)	3.8 (2 to 7.1)		
hSBA-MenY [N=91;28]	79.2 (52.5 to 119.3)	15.1 (6.3 to 36.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 44 after primary vaccination

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=89;31]	4.8 (3.4 to 6.7)	2.8 (2.1 to 3.7)		
hSBA-MenC [N=82;31]	36.4 (23.1 to 57.2)	38.8 (13.3 to 113.2)		
hSBA-MenW-135 [N=87;30]	64.3 (42.7 to 96.8)	5.2 (2.8 to 9.5)		
hSBA-MenY [N=76;26]	126.7 (78 to 205.7)	16.8 (16.8 to 44.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs

End point title	Number of subjects with any SAEs

End point description:

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

End point type	Secondary

End point timeframe:

Up to Month 32, 44, 56 and 68

End point values	Nimenrix Month 32 Group	Nimenrix Month 44 Group	Nimenrix Month 56 Group	Menjugate Month 32 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	199	193	193	72
Units: Subjects	0	0	0	0

End point values	Menjugate Month 44 Group	Menjugate Month 56 Group	Nimenrix Month 68 Group	Menjugate Month 68 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	68	67	179	62
Units: Subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 56 months after the primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	65		
Units: Subjects				
rSBA-MenA [N=186;65]	107	10		
rSBA-MenC [N=186;65]	65	32		
rSBA-MenW-135 [N=186;65]	123	10		
rSBA-MenY [N=186;64]	139	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 68 months after the primary vaccination

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Subjects				
rSBA-MenA	107	12		
rSBA-MenC	38	25		
rSBA-MenW-135	84	8		
rSBA-MenY	118	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 56 months after the primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	185	63		
Units: Subjects				
rSBA-MenA [N=184;54]	184	18		
rSBA-MenC [N=182;63]	179	63		
rSBA-MenW-135 [N=185;61]	184	29		
rSBA-MenY [N=184;61]	184	34		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres ≥1:128

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 68 months after the primary vaccination

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	59		
Units: Subjects				
rSBA-MenA [N=176;51]	176	19		
rSBA-MenC [N=174;59]	172	59		
rSBA-MenW-135 [N=177;58]	176	27		
rSBA-MenY [N=176;57]	176	32		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type	Secondary

End point timeframe:

At 56 months after the primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	181	65		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=181;65]	120.1 (87 to 165.9)	9.8 (6.4 to 15)		
rSBA-MenC [N=181;65]	30.5 (22.6 to 41.1)	69 (36.9 to 128.9)		
rSBA-MenW-135 [N=181;65]	158.3 (112.4 to 222.9)	10.3 (6.4 to 16.6)		
rSBA-MenY [N=181;64]	233.2 (166 to 327.6)	9 (6 to 13.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens
End point description:	
These analyses were performed by the Health Protection Agency (HPA) laboratory	
End point type	Secondary
End point timeframe:	
At 68 months after the primary vaccination	

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=178;61]	129.5 (93.5 to 179.3)	11.1 (7 to 17.7)		
rSBA-MenC [N=178;61]	14.2 (10.8 to 18.7)	44.5 (23.7 to 83.6)		
rSBA-MenW-135 [N=178;61]	59.2 (39.3 to 89.2)	7.8 (5 to 12.1)		
rSBA-MenY [N=178;61]	139.4 (96 to 202.5)	6.8 (4.6 to 10.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 56 months after the primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	185	63		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=184;54]	6748.6 (5931.4 to 7678.5)	27.9 (14.5 to 53.6)		
rSBA-MenC [N=182;63]	2612.4 (2133.4 to 3199)	5327.5 (3508.6 to 8089.4)		
rSBA-MenW-135 [N=185;61]	9350.9 (8134 to 10749.9)	78.1 (48.2 to 126.7)		
rSBA-MenY [N=184;61]	8418.8 (7265.3 to 9755.5)	94.7 (59.3 to 151.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

End point description:

These analyses were performed by the GSK laboratory

End point type	Secondary

End point timeframe:

At 68 months after the primary vaccination

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	177	59		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=176;51]	6875.3 (6005.7 to 7870.9)	31.9 (16.1 to 63.1)		
rSBA-MenC [N=174;59]	2911.5 (2354.6 to 3600.2)	5393 (3436.2 to 8464.2)		
rSBA-MenW-135 [N=177;58]	9587.1 (8337.7 to 11023.7)	77.4 (47.4 to 126.3)		
rSBA-MenY [N=176;57]	8723 (7530.3 to 10104.7)	95.8 (58.9 to 155.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 56 after primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Subjects				
hSBA-MenA [N=89;33]	53	19		
hSBA-MenC [N=86;31]	66	21		
hSBA-MenW-135 [N=83;30]	69	13		
hSBA-MenY [N=89;31]	79	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 68 after primary vaccination

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172	59		
Units: Subjects				
hSBA-MenA [N=170;59]	70	23		
hSBA-MenC [N=172;57]	134	43		
hSBA-MenW-135 [N=159;52]	125	19		
hSBA-MenY [N=159;58]	116	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point description:

This analysis was performed on 50% of the subjects in each group

End point type	Secondary

End point timeframe:

At Month 56 after primary vaccination

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=89;33]	10.6 (7.6 to 14.9)	7.6 (5 to 11.8)		
hSBA-MenC [N=86;31]	20.6 (13.8 to 30.8)	31.2 (11.5 to 85)		
hSBA-MenW-135 [N=83;30]	59.3 (40.2 to 87.6)	9.2 (4.7 to 18.2)		
hSBA-MenY [N=89;31]	117.9 (80.8 to 171.9)	35.7 (16.8 to 75.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens
End point description:	
This analysis was performed on 50% of the subjects in each group	
End point type	Secondary
End point timeframe:	
At Month 68 after primary vaccination	

End point values	Nimenrix Month 68 Group	Menjugate Month 68 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172	59		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=170;59]	6.9 (5.4 to 8.9)	4.5 (3.3 to 6)		
hSBA-MenC [N=172;57]	28.4 (21.2 to 37.9)	34.3 (19 to 61.9)		
hSBA-MenW-135 [N=159;52]	56.7 (41.5 to 77.3)	8.1 (4.7 to 13.8)		
hSBA-MenY [N=159;58]	56.3 (39.5 to 80.3)	13.3 (7 to 25.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres ≥1:8

End point description:

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Subjects				
rSBA-MenA	165	55		
rSBA-MenC	165	55		
rSBA-MenW-135	165	55		
rSBA-MenY	165	55		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres ≥1:128

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres ≥1:128

End point description:

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Subjects				
rSBA-MenA	165	55		
rSBA-MenC	165	55		
rSBA-MenW-135	165	55		
rSBA-MenY	165	55		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY meningococcal antigens

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY meningococcal antigens

End point description:

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	5613 (4946.3 to 6369.4)	3521.1 (2912.5 to 4256.9)		
rSBA-MenC	5314.6 (4596.2 to 6145.4)	7042.2 (5317.4 to 9326.5)		
rSBA-MenW-135	14750.6 (12779.6 to 17025.6)	10540.4 (8455.2 to 13139.8)		
rSBA-MenY	7954.6 (7167.8 to 8827.8)	5829.2 (4725.6 to 7190.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibodies

End point title	Number of subjects with a vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibodies

End point description:

Vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY is defined as rSBA antibody titers ≥1:32, for initially seronegative subjects (i.e. pre-vaccination rSBA antibody titres <1:8) and at least a 4-fold increase in rSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination rSBA antibody titres ≥1:8).

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Subjects				
rSBA-MenA-Post-booster status Total	147	54		
rSBA-MenC-Post-booster status Total	161	48		
rSBA-MenW-Post-booster status Total	157	54		
rSBA-MenY-Post-booster status Total	156	54		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:4

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers ≥1:8, for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres <1:4) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres ≥1:4).

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	54		
Units: Subjects				
hSBA-MenA [N=163;53]	163	46		
hSBA-MenC [N=161;54]	161	54		
hSBA-MenW-135 [N=156;52]	156	50		
hSBA-MenY [N=160;54]	160	52		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres ≥1:8

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers ≥1:8, for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres <1:4) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres ≥1:4).

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	54		
Units: Subjects				
hSBA-MenA [N=163;53]	163	46		
hSBA-MenC [N=161;54]	161	54		
hSBA-MenW-135 [N=156;52]	156	50		
hSBA-MenY [N=160;54]	160	52		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers ≥1:8, for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres <1:4) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres ≥1:4).

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	54		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=163;53]	1376.5 (1138.2 to 1664.6)	101.2 (59.3 to 172.8)		
hSBA-MenC [N=161;54]	11986.8 (10085.2 to 14247)	13692.2 (10094.2 to 18572.8)		
hSBA-MenW-135 [N=156;52]	14582.1 (12448.5 to 17081.5)	235.7 (152 to 365.5)		
hSBA-MenY [N=160;54]	12835.9 (11074.4 to 14877.5)	527.3 (356.5 to 779.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with a vaccine response to hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibodies

End point title	Number of subjects with a vaccine response to hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibodies

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers ≥1:8, for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres <1:4) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres ≥1:4).

End point type	Secondary

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	52		
Units: Subjects				
hSBA-MenA-Post-booster status Total [159;52]	156	43		
hSBA-MenC-Post-booster status Total [156;50]	153	46		
hSBA-MenW-Post-booster status Total [139;45]	136	34		
hSBA-MenY-Post-booster status Total [144;51]	142	35		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 pain was defined as crying when limb was moved/spontaneously painful. Grade 3 swelling/redness was defined as swelling/redness larger than (>) 50 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity.

End point type	Secondary

End point timeframe:

During the 4-day period (Days 0-3) following the booster vaccination.

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	171	60		
Units: Subjects				
Any Pain	113	35		
Grade 3 Pain	7	4		
Any Redness	62	25		
Grade 3 Redness	8	4		
Any Swelling	52	19		
Grade 3 Swelling	4	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms

End point title	Number of subjects with solicited general symptoms

End point description:

Assessed solicited general symptoms were Fatigue, Gastrointestinal symptoms (Gastro. symptoms), Headache and Temperature (axillary temperature higher than [≥] 37.5 degrees Celsius [°C]). Any = Occurrence of the specified solicited general symptom, regardless of intensity or relationship to vaccination. Related = Occurrence of the specified symptom assessed by the investigators as causally related to vaccination. Grade 3 Fatigue = Fatigue that prevented normal activity. Grade 3 Gastro. symptoms = Gastro. symptoms that prevented normal everyday activities. Grade 3 Headache = Headache that prevented normal acitivity. Grade 3 Fever = Rectal temperature higher than (>) 39.5°C.

End point type	Secondary

End point timeframe:

During the 4-day period (Days 0-3) following the booster vaccination.

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	169	58		
Units: Subjects				
Any Fatigue	38	12		
Grade 3 Fatigue	3	0		
Related Fatigue	28	10		
Any Gastro. Symptoms	19	7		
Grade 3 Gastro. Symptoms	2	1		
Related Gastro. Symptoms	10	3		
Any Headache	43	10		
Grade 3 Headache	7	0		
Related Headache	27	8		
Any Temperature/Axillary	11	5		
Grade 3 Temperature/Axillary	0	0		
Related Temperature/Axillary	9	3		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

An AE is 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.

End point type	Secondary

End point timeframe:

During the 31-day period (Days 0-30) following the booster vaccination.

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Subjects				
Any AEs	26	8		

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, result in disability/incapacity.

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Subjects				
Any SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any new onset of chronic illnesses (NOCIs)

End point title	Number of subjects with any new onset of chronic illnesses (NOCIs)

End point description:

New onset of chronic illnesses (NOCIs) included: autoimmune disorders, asthma, type I diabetes and allergies.

End point type	Secondary

End point timeframe:

During the 31-day period (Days 0-30) following the booster vaccination.

End point values	Nimenrix Month 69 Group	Menjugate Month 69 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Subjects				
Any NOCIs	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day post-vaccination period, Unsolicited AEs during the 31-day post-vaccination period, SAEs during the entire study period.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Nimenrix Month 32 Group
Reporting group description: -	
Reporting group title	Nimenrix Month 44 Group
Reporting group description: -	
Reporting group title	Menjugate Month 32 Group
Reporting group description: -	
Reporting group title	Menjugate Month 44 Group
Reporting group description: -	
Reporting group title	Nimenrix Month 56 Group
Reporting group description: -	
Reporting group title	Menjugate Month 56 Group
Reporting group description: -	
Reporting group title	Nimenrix Month 68 Group
Reporting group description: -	
Reporting group title	Menjugate Month 68 Group
Reporting group description: -	
Reporting group title	Nimenrix Month 69 Group
Reporting group description: -	
Reporting group title	Menjugate Month 68 Group

Reporting group description: -

Serious adverse events	Nimenrix Month 32 Group	Nimenrix Month 44 Group	Menjugate Month 32 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	Menjugate Month 44 Group	Nimenrix Month 56 Group	Menjugate Month 56 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0		

Serious adverse events	Nimenrix Month 68 Group	Menjugate Month 68 Group	Nimenrix Month 69 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 193 (0.00%)	0 / 67 (0.00%)	0 / 179 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Menjugate Month 68 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 62 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Nimenrix Month 32 Group	Nimenrix Month 44 Group	Menjugate Month 32 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed[4]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 192 (0.00%)	0 / 193 (0.00%)	0 / 72 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Menjugate Month 44 Group	Nimenrix Month 56 Group	Menjugate Month 56 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed[4]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 68 (0.00%)	0 / 193 (0.00%)	0 / 67 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Nimenrix Month 68 Group	Menjugate Month 68 Group	Nimenrix Month 69 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 193 (0.00%)	0 / 67 (0.00%)	113 / 179 (63.13%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	0 / 193 (0.00%)	0 / 67 (0.00%)	113 / 171 (66.08%)
occurrences (all)	0	0	113
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	0 / 193 (0.00%)	0 / 67 (0.00%)	62 / 171 (36.26%)
occurrences (all)	0	0	62
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 193 (0.00%)	0 / 67 (0.00%)	52 / 171 (30.41%)
occurrences (all)	0	0	52
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed[4]	0 / 193 (0.00%)	0 / 67 (0.00%)	38 / 169 (22.49%)
occurrences (all)	0	0	38
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[5]	0 / 193 (0.00%)	0 / 67 (0.00%)	19 / 169 (11.24%)
occurrences (all)	0	0	19
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[6]	0 / 193 (0.00%)	0 / 67 (0.00%)	43 / 169 (25.44%)
occurrences (all)	0	0	43
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	0 / 193 (0.00%)	0 / 67 (0.00%)	11 / 169 (6.51%)
occurrences (all)	0	0	11

Non-serious adverse events	Menjugate Month 68 Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 62 (56.45%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[1]	35 / 60 (58.33%)		
occurrences (all)	35		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed[2]	25 / 60 (41.67%)		
occurrences (all)	25		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	19 / 60 (31.67%)		
occurrences (all)	19		
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed[4]	12 / 58 (20.69%)		
occurrences (all)	12		
Gastrointestinal symptoms			
alternative assessment type: Systematic			
subjects affected / exposed[5]	7 / 58 (12.07%)		
occurrences (all)	7		
Headache			
alternative assessment type: Systematic			
subjects affected / exposed[6]	10 / 58 (17.24%)		
occurrences (all)	10		
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	5 / 58 (8.62%)		
occurrences (all)	5		

Notes:

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

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

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

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

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

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 August 2010	This amendment has been done to answer the requests of the French and German ethics committees to not use Menjugate as a booster vaccination since Menjugate has no booster indication in France and also to not use Menveo as a booster vaccination since Menveo is currently not licensed for the age group in this study and has no booster indication.
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)-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY titres ≥1:8 at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate. In addition, to support the data obtained by rSBA testing, antibody titres and concentrations against meningococcal polysaccharides were planned to be assessed by human (h)SBA testing and ELISA (anti-polysaccharides [PS] testing) at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate and at Month 69, one month after the MenACWY-TT booster vaccination. The sponsor decided not to perform the ELISA testing at all time points 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 [CDC, 2011; WHO, 2006]. Although antibody concentrations will not be determined by ELISA at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate and at Month 69, one month after the MenACWY-TT booster vaccination, all subjects will be informed of their rSBA and hSBA 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 meningococcal vaccines. • The list of abbreviations and reference list have been updated according to changes made throughout the protocol. The authors list has 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