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	v3 (current)
This version publication date	10 December 2020
First version publication date	24 May 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	113977

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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:

Out of 282 subjects participating to the study, 271 participated to Month 32-44 period, 261 to Month 44-56, 260 to Month 56-68, and 282 to Month 68-69 booster period.
Out of 282 subjects participating to Month 68-69 booster period, 41 subjects had a subject number allocated but received no vaccine dose, hence only 241 started this phase.

Pre-assignment

Screening details:

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

Period 1

Period 1 title	Persistence Phase (Month 32-44)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 1[1]	Nimenrix Group	Menjugate 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: Among the 282 subjects participating to the study, 271 subjects started the Persistence epoch Month 32 starting Month 32 and ending Month 44.

Period 2

Period 2 title	Persistence Phase (Month 44-56)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group	Menjugate 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: The number of subjects who started each period depends on the number of subjects available at the time.

Period 3

Period 3 title	Persistence Phase (Month 56-68)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group	Menjugate 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: The number of subjects who started each period depends on the number of subjects available at the time.

Period 4

Period 4 title	Booster Phase (Month 68-69)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nimenrix Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 Group

Arm description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

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 4[4]	Nimenrix Group	Menjugate Group
Started	179	62
Completed	174	60
Not completed	5	2
Consent withdrawn by subject	-	1
Lost to follow-up	5	1

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: The number of subjects who started each period depends on the number of subjects available at the time.

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix Group
Reporting group description:	
Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.	
Reporting group title	Menjugate Group
Reporting group description:	
Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.	

Reporting group values	Nimenrix Group	Menjugate Group	Total
Number of subjects	199	72	271
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	199	72	271
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	8.4	8.1	
standard deviation	± 2.58	± 2.42	-
Sex: Female, Male Units: Participants			
Female	103	34	137
Male	96	38	134
Race/Ethnicity, Customized Units: Subjects			
White - Caucasian/European Heritage	169	61	230
Other	8	2	10
African heritage / African American	7	2	9
American Indian or Alaskan native	0	0	0
Asian - Central/South Asian heritage	1	0	1
Asian - East Asian heritage	1	1	2
Asian - Japanese heritage	0	0	0
Asian - South East Asian heritage	1	0	1

Native Hawaiian or other pacific islander	0	0	0
White - Arabic / North African heritage	12	6	18

End points

End points reporting groups

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Primary: Number of subjects with serum bactericidal assay, using baby rabbit complement, against Neisseria meningitides serogroup A, C, W-135, Y (rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY) antibody titers was greater than or equal to (≥) 1:8, at Month 32.

End point title	Number of subjects with serum bactericidal assay, using baby rabbit complement, against Neisseria meningitides serogroup A, C, W-135, Y (rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY) antibody titers was greater than or equal to (≥) 1:8, at Month 32.[1]

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Primary

End point timeframe:

At Month 32, post-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 Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	69		
Units: Participants				
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 and rSBA-MenY antibody titers ≥ 1:8, at Month 44.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:8, at Month 44.[2]

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Primary

End point timeframe:

At Month 44, post-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 Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	66		
Units: Participants				
rSBA-MenA	162	17		
rSBA-MenC	70	30		
rSBA-MenW-135	129	7		
rSBA-MenY	118	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:8, at Month 56.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:8, at Month 56.[3]

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Primary

End point timeframe:

At Month 56, post-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 Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	65		
Units: Participants				
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 and rSBA-MenY antibody titers ≥ 1:8, at Month 68.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:8, at Month 68.[4]

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Primary

End point timeframe:

At Month 68, post-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 Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Participants				
rSBA-MenA	154	18		
rSBA-MenC	71	38		
rSBA-MenW-135	94	9		
rSBA-MenY	127	8		

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 titers ≥ 1:128, at Month 32.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:128, at Month 32.

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:128. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 32, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	69		
Units: Participants				
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 and rSBA-MenY antibody titers ≥ 1:128, at Month 44.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:128, at Month 44.

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:128. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 44, post-primary vaccination

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

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 titers ≥ 1:128, at Month 56.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:128, at Month 56.

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:128. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 56, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	65		
Units: Participants				
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 and rSBA-MenY antibody titers ≥ 1:128, at Month 68.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:128, at Month 68.

End point description:

The pre-defined cut-off value of the assay for the rSBA titers was greater than or equal to (≥) 1:128. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 68, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Participants				
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: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY, at Month 32.

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

	and rSBA-MenY, at Month 32.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 32, post-primary vaccination

End point values	Nimenrix Group	Menjugate 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 [N=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 and rSBA-MenY, at Month 44.

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY, at Month 44.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 44, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	66		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	307.5 (223.7 to 422.8)	13.5 (8 to 23)		

rSBA-MenC	14.5 (10.9 to 19.2)	31 (16.6 to 58)		
rSBA-MenW-135	103.5 (72.5 to 147.6)	5.9 (4.3 to 8.1)		
rSBA-MenY	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 and rSBA-MenY, at Month 56.

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY, at Month 56.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 56, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	65		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA [N=186;65]	120.1 (87.0 to 165.9)	9.8 (6.4 to 15.0)		
rSBA-MenC [N=186;65]	30.5 (22.6 to 41.1)	69.0 (36.9 to 128.9)		
rSBA-MenW-135 [N=186;65]	158.3 (112.4 to 222.9)	10.3 (6.4 to 16.6)		
rSBA-MenY [N=186;64]	233.2 (166.0 to 327.6)	9.0 (6.0 to 13.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY, at Month 68.

End point title	Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY, at Month 68.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the

Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 68, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	178	61		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	129.5 (93.5 to 179.3)	11.1 (7.0 to 17.7)		
rSBA-MenC	14.2 (10.8 to 18.7)	44.5 (23.7 to 83.6)		
rSBA-MenW-135	59.2 (39.3 to 89.2)	7.8 (5.0 to 12.1)		
rSBA-MenY	139.4 (96.0 to 202.5)	6.8 (4.6 to 10.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay, using human complement, against N. meningitides serogroup A, C, W-135, Y (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titers ≥ 1:4 and ≥ 1:8, at Month 32.

End point title	Number of subjects with serum bactericidal assay, using human complement, against N. meningitides serogroup A, C, W-135, Y (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titers ≥ 1:4 and ≥ 1:8, at Month 32.

End point description:

The pre-defined cut-off values of the assay for the hSBA titers were greater than or equal to (≥) 1:4 and ≥ 1:8. These analyses have been performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 32, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	91	34		
Units: Participants				
hSBA-MenA, ≥ 1:4 [N=90;34]	24	5		
hSBA-MenC, ≥ 1:4 [N=90;33]	86	30		

hSBA-MenW-135, ≥ 1:4 [N=86;23]	73	4		
hSBA-MenY, ≥ 1:4 [N=91;28]	74	13		
hSBA-MenA, ≥ 1:8 [N=90;34]	23	5		
hSBA-MenC, ≥ 1:8 [N=90;33]	86	30		
hSBA-MenW-135, ≥ 1:8 [N=86;23]	73	4		
hSBA-MenY, ≥ 1:8 [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 titers ≥ 1:4 and ≥ 1:8, at Month 44.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers ≥ 1:4 and ≥ 1:8, at Month 44.

End point description:

The pre-defined cut-off values of the assay for the hSBA titers were greater than or equal to (≥) 1:4 and ≥ 1:8. These analyses have been performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 44, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	31		
Units: Participants				
hSBA-MenA, ≥ 1:4 [N=89;31]	26	5		
hSBA-MenC, ≥ 1:4 [N=82;31]	63	20		
hSBA-MenW-135, ≥ 1:4 [N=87;30]	70	8		
hSBA-MenY, ≥ 1:4 [N=76;26]	63	12		
hSBA-MenA, ≥ 1:8 [N=89;31]	23	5		
hSBA-MenC, ≥ 1:8 [N=82;31]	63	20		
hSBA-MenW-135, ≥ 1:8 [N=87;30]	70	8		
hSBA-MenY, ≥ 1:8 [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 titers ≥ 1:4 and ≥ 1:8, at Month 56.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers ≥ 1:4 and ≥ 1:8, at

	Month 56.

End point description:

The pre-defined cut-off values of the assay for the hSBA titers were greater than or equal to (≥) 1:4 and ≥ 1:8. These analyses have been performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 56, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	33		
Units: Participants				
hSBA-MenA, ≥ 1:4 [N=89;33]	53	19		
hSBA-MenC, ≥ 1:4 [N=86;31]	66	21		
hSBA-MenW-135, ≥ 1:4 [N=83;30]	69	13		
hSBA-MenY, ≥ 1:4 [N=89;31]	79	22		
hSBA-MenA, ≥ 1:8 [N=89;33]	53	19		
hSBA-MenC, ≥ 1:8 [N=86;31]	64	21		
hSBA-MenW-135, ≥ 1:8 [N=83;30]	69	13		
hSBA-MenY, ≥ 1:8 [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 titers ≥ 1:4 and ≥ 1:8, at Month 68.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers ≥ 1:4 and ≥ 1:8, at Month 68.

End point description:

The pre-defined cut-off values of the assay for the hSBA titers were greater than or equal to (≥) 1:4 and ≥ 1:8. These analyses have been performed in all subjects, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 68, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	172	59		
Units: Participants				
hSBA-MenA, ≥ 1:4 [N=170;59]	70	23		
hSBA-MenC, ≥ 1:4 [N=172;57]	134	43		
hSBA-MenW-135, ≥ 1:4 [N=159;52]	125	19		
hSBA-MenY, ≥ 1:4 [N=159;58]	116	24		
hSBA-MenA, ≥ 1:8 [N=170;59]	69	21		
hSBA-MenC, ≥ 1:8 [N=172;57]	130	43		
hSBA-MenW-135, ≥ 1:8 [N=159;52]	125	19		
hSBA-MenY, ≥ 1:8 [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, at Month 32.

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY, at Month 32.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 32, post-primary vaccination

End point values	Nimenrix Group	Menjugate 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, at Month 44.

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY, at Month 44.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 44, post-primary vaccination

End point values	Nimenrix Group	Menjugate 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: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY, at Month 56.

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY, at Month 56.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed on 50% of the subjects in each group, by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 56, post-primary vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	89	33		
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-MenA [N=89;33]	10.6 (7.6 to 14.9)	7.6 (5.0 to 11.8)		
hSBA-MenC [N=86;31]	20.6 (13.8 to 30.8)	31.2 (11.5 to 85.0)		
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, at Month 68.

End point title	Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY, at Month 68.

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 68, post-primary vaccination

End point values	Nimenrix Group	Menjugate 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 6.0)		
hSBA-MenC [N=172;57]	28.4 (21.2 to 37.9)	34.3 (19.0 to 61.0)		
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 (7.0 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 titers ≥ 1:128 and 1:8.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ≥ 1:128 and 1:8.

End point description:

The pre-defined cut-off values of the assay for the rSBA titers were greater than or equal to (≥) 1:128 and ≥ 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Participants				
rSBA-MenA, ≥ 1:8	165	55		
rSBA-MenC, ≥ 1:8	165	55		
rSBA-MenW-135, ≥ 1:8	165	55		
rSBA-MenY, ≥ 1:8	165	55		
rSBA-MenA, ≥ 1:128	165	55		
rSBA-MenC, ≥ 1:128	165	55		
rSBA-MenW-135, ≥ 1:128	165	55		
rSBA-MenY, ≥ 1:128	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

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

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA	5613.0 (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 hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers ≥ 1:4 and 1:8.

End point title	Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titers ≥ 1:4 and 1:8.

End point description:

The pre-defined cut-off values of the assay for the hSBA titers were greater than or equal to (≥) 1:4 and ≥ 1:8. These analyses have been performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	54		
Units: Participants				
hSBA-MenA, ≥ 1:4 [N=163;53]	163	46		
hSBA-MenC, ≥ 1:4 [N=161;54]	161	54		
hSBA-MenW-135, ≥ 1:4 [N=156;52]	156	50		
hSBA-MenY, ≥ 1:4 [N=160;54]	160	52		
hSBA-MenA, ≥ 1:8 [N=163;53]	163	46		
hSBA-MenC, ≥ 1:8 [N=161;54]	161	54		
hSBA-MenW-135, ≥ 1:8 [N=156;52]	156	50		
hSBA-MenY, ≥ 1:8 [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

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

End point description:

Antibody titers were presented as geometric mean titers (GMTs). These analyses were performed by the Health Protection Agency (HPA) laboratory.

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate 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 14247.0)	13692.2 (10094.2 to 18572.8)		
hSBA-MenW-135 [N=156;52]	14582.1 (12448.5 to 17081.5)	235.7 (152.0 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 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 was defined as rSBA antibody titers ≥1:32, for initially seronegative subjects (i.e. pre-vaccination rSBA antibody titers <1:8) and at least a 4-fold increase in rSBA antibody titers from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination rSBA antibody titers ≥1:8).

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	165	55		
Units: Participants				
rSBA-MenA	147	54		
rSBA-MenC	161	48		
rSBA-MenW-135	157	54		
rSBA-MenY	156	54		

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 was defined as hSBA antibody titers ≥ 1:8, for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titers <1:4) and at least a 4-fold increase in hSBA antibody titers from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titers ≥1:4).

End point type	Secondary

End point timeframe:

At Month 69, one month post-booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	52		
Units: Participants				
hSBA-MenA [N=159;52]	156	43		
hSBA-MenC [N=156;50]	153	46		
hSBA-MenW-135 [N=139;45]	136	34		
hSBA-MenY [N=144;51]	142	35		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any and grade 3 solicited local symptoms

End point description:

Solicited local symptoms assessed 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" was defined as incidence of the specified symptom regardless of intensity.

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	171	60		
Units: Participants				
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 any, grade 3 and solicited general symptoms

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

End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal 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 Gastrointestinal symptoms = Gastrointestinal 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 (Days 0-3) period following the booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	169	58		
Units: Participants				
Any Fatigue	38	12		
Grade 3 Fatigue	3	0		
Related Fatigue	28	10		
Any Gastrointestinal symptoms	19	7		
Grade 3 Gastrointestinal symptoms	2	1		
Related Gastrointestinal symptoms	10	3		
Any Headache	43	10		
Grade 3 Headache	7	0		
Related Headache	27	8		
Any Temperature	11	5		
Grade 3 Temperature	0	0		
Related Temperature	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 unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Participants	26	8		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with serious adverse events (SAEs)

End point description:

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

End point type	Secondary

End point timeframe:

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

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Participants	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 (Days 0-30) period following the booster vaccination

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	179	62		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events SAEs

End point title	Number of subjects with serious adverse events SAEs

End point description:

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

End point type	Secondary

End point timeframe:

Up to Month 32, 44, 56 and 68

End point values	Nimenrix Group	Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	199	72		
Units: Participants				
Up to Month 32 [N=199;72]	0	0		
Up to Month 44 [N=193;68]	0	0		
Up to Month 56 [N=193;67]	0	0		
Up to Month 68 [N=179;62]	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 4-day (Days 0-3) post-vaccination period; Unsolicited AEs: during the 31-day (Days 0-30) post-vaccination period; SAEs: during the entire study period (Month 32 up to Month 69).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Menjugate Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Menjugate vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Reporting group title	Nimenrix Group

Reporting group description:

Healthy male or female subjects aged 2 through 10 years old, who were primed with one dose of Nimenrix vaccine during the primary 111414 study (NCT00674583), additionally received one booster dose of Nimenrix vaccine in the current study, at Month 68, administered intramuscularly in the deltoid region of the non-dominant arm.

Serious adverse events	Menjugate Group	Nimenrix Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 62 (0.00%)	0 / 179 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Menjugate Group	Nimenrix Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 62 (77.42%)	130 / 179 (72.63%)	
Nervous system disorders			
Headache			
subjects affected / exposed	10 / 62 (16.13%)	43 / 179 (24.02%)	
occurrences (all)	10	49	
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	12 / 62 (19.35%)	38 / 179 (21.23%)	
occurrences (all)	12	38	
Pain			
subjects affected / exposed	35 / 62 (56.45%)	113 / 179 (63.13%)	
occurrences (all)	35	113	
Pyrexia			
subjects affected / exposed	8 / 62 (12.90%)	17 / 179 (9.50%)	
occurrences (all)	8	17	
Swelling			
subjects affected / exposed	19 / 62 (30.65%)	52 / 179 (29.05%)	
occurrences (all)	19	52	
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	7 / 62 (11.29%)	19 / 179 (10.61%)	
occurrences (all)	7	19	
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	25 / 62 (40.32%)	62 / 179 (34.64%)	
occurrences (all)	25	62	

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