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	v1
This version publication date	01 April 2016
First version publication date	24 May 2015

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	Interim
Date of interim/final analysis	07 July 2014
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:

Immunogenicity
Persistence
At 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate.
•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	68 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	0

months)	
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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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: The difference in subjects is further detailed in the pre-assignment period.

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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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 completing a study period returned for the next one.

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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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 completing a study period returned for the next one.

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	

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[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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

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	167	15		
rSBA-MenC	124	53		
rSBA-MenW-135	149	5		
rSBA-MenY	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 scope of this primary endpoint was descriptive, no statistical analyses were conducted.

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	162	17		
rSBA-MenC	70	30		
rSBA-MenW-135	129	7		
rSBA-MenY	118	4		

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 ≥1:8

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

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	191	25		
rSBA-MenC	189	67		
rSBA-MenW-135	192	52		
rSBA-MenY	191	51		

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 ≥1:8

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

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	187	24		
rSBA-MenC	186	64		
rSBA-MenW-135	188	49		
rSBA-MenY	187	49		

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	140	9		
rSBA-MenC	69	35		
rSBA-MenW-135	136	5		
rSBA-MenY	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	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, 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	191	19		
rSBA-MenC	186	67		
rSBA-MenW-135	191	30		
rSBA-MenY	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	187	18		
rSBA-MenC	183	64		
rSBA-MenW-135	187	29		
rSBA-MenY	187	32		

Statistical analyses

No statistical analyses for this end point

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

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

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	196.3 (144.1 to 267.2)	8 (5.5 to 11.7)		
rSBA-MenC	34.8 (26 to 46.4)	86.5 (47.3 to 158.1)		
rSBA-MenW-135	213.9 (149.3 to 306.6)	5.6 (4.2 to 7.6)		
rSBA-MenY	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

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

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	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, rSBA-MenY

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

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	6733.3 (5927 to 7649.3)	27.2 (14.4 to 51.1)		
rSBA-MenC	2588 (2124.5 to 3152.7)	5135.3 (3436.5 to 7674.1)		
rSBA-MenW-135	8959.1 (7828.9 to 10252.5)	77.9 (49.4 to 122.9)		
rSBA-MenY	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

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

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	6633.2 (5830.3 to 7546.6)	26.9 (14.1 to 51.3)		
rSBA-MenC	2609 (2134.9 to 3188.3)	5120.1 (3432 to 7638.4)		
rSBA-MenW-135	9158.4 (7975 to 10517.4)	76.9 (47.9 to 123.6)		
rSBA-MenY	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 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:

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	24	5		
hSBA-MenC	86	30		
hSBA-MenW-135	73	4		
hSBA-MenY	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:

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	26	5		
hSBA-MenC	63	20		
hSBA-MenW-135	70	8		
hSBA-MenY	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:

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	23	5		
hSBA-MenC	86	30		
hSBA-MenW-135	73	4		
hSBA-MenY	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:

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	23	5		
hSBA-MenC	63	20		
hSBA-MenW-135	70	8		
hSBA-MenY	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

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

End point description:

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	4.6 (3.3 to 6.3)	2.7 (2.1 to 3.4)		
hSBA-MenC	75.9 (53.4 to 107.9)	82.2 (34.6 to 195.8)		

hSBA-MenW-135	69.9 (48.2 to 101.5)	3.8 (2 to 7.1)		
hSBA-MenY	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

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

End point description:

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	4.8 (3.4 to 6.7)	2.8 (2.1 to 3.7)		
hSBA-MenC	36.4 (23.1 to 57.2)	38.8 (13.3 to 113.2)		
hSBA-MenW-135	64.3 (42.7 to 96.8)	5.2 (2.8 to 9.5)		
hSBA-MenY	126.7 (78 to 205.7)	16.8 (6.3 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:

End point type	Secondary

End point timeframe:

Up to Month 32, 44 and 56

End point values	Nimenrix Month 56 Group	Menjugate Month 56 Group	Nimenrix Month 32 Group	Menjugate Month 32 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	193	67	199	72
Units: Subjects	0	0	0	0

End point values	Nimenrix Month 44 Group	Menjugate Month 44 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	193	68		
Units: Subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Subjects with solicited local and general symptoms during the 4-day period (Days 0-3) following the booster vaccination. Unsolicited adverse events, serious adverse events and specific during the 31-day period (Days 0-30) following the booster vaccinaton.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Nimenrix Group until month 32
Reporting group description: -	
Reporting group title	Menjugate Group until month 32
Reporting group description: -	
Reporting group title	Nimenrix Group until month 44
Reporting group description: -	
Reporting group title	Menjugate Group until month 44

Reporting group description: -

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

Serious adverse events	Menjugate Group until month 44		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 68 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Nimenrix Group until month 32	Menjugate Group until month 32	Nimenrix Group until month 44
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 192 (0.00%)	0 / 72 (0.00%)	0 / 193 (0.00%)

Non-serious adverse events	Menjugate Group		

	until month 44		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 68 (0.00%)		

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were collected up to the present timepoint in the study.

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