Clinical trial results:
A Phase 3b, Controlled, Open-Label, Multi-Center Study to Evaluate Safety and Immunogenicity of a Single Dose of GlaxoSmithKline's Meningococcal ACWY Conjugate Vaccine (Menveo),Administered to Healthy Individuals 15 through 55 years of age , approximately 4-6 years after primary ACWY vaccination

Summary

EudraCT number	2016-003186-25
Trial protocol	Outside EU/EEA
Global end of trial date	07 December 2017

Results information

Result version number	v1
This version publication date	20 July 2018
First version publication date	20 July 2018

Trial information

Trial identification

Sponsor protocol code	205352

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02986854
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, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, 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	06 April 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 July 2017
Global end of trial reached?	Yes
Global end of trial date	07 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menveo, as measured by the percentage of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination
2. To demonstrate a sufficient immune response following a booster dose of MenACWY-CRM (Menveo) vaccine, given to subjects who previously received Menactra, as measured by the percentage of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y at Day 29 after vaccination

Protection of trial subjects:

All subjects were observed for at least 30 minutes after vaccine administration with appropriate medical treatment readily available in case of anaphylaxis. Vaccine was administered by qualified and trained personnel and vaccine was given only to eligible subjects that had no contraindications to any components of the vaccine. Subjects were followed for 6 months for selected safety assessments.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 December 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 694
Country: Number of subjects enrolled	Puerto Rico: 10
Worldwide total number of subjects	704
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0

Adolescents (12-17 years)	480
Adults (18-64 years)	224
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 1 center in Puerto Rico and 37 centers in Unites States.

Pre-assignment

Screening details:

704 subjects were enrolled in this study. Out of 704 enrolled, 701 received the study vaccine.

Pre-assignment period milestones

Number of subjects started	704
Number of subjects completed	701

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Not randomized: 3

Period 1

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

Blinding implementation details:

The study was an open-labelled study. Therefore, no blinding procedures were utilized.

Arms

Are arms mutually exclusive?	Yes
Arm title	Menveo-Menveo Group

Arm description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

Arm title	Menactra-Menveo Group

Arm description:

Healthy subjects,15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

Arm type	Experimental
Investigational medicinal product name	Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

Arm title	Naive Group

Arm description:

Healthy subjects,15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.

Arm type	Control
Investigational medicinal product name	Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate Vaccine (Menveo)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One intramuscular injection of MenACWY-CRM at Day 1.

Number of subjects in period 1[1]	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group
Started	301	300	100
Completed	298	288	97
Not completed	3	12	3
Consent withdrawn by subject	-	1	1
Lost to follow-up	3	11	2

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: Number of subjects reported in the baseline period are subjects who received vaccination (exposed set). Out of 704 subjects enrolled worldwide, 3 subjects were not randomized into any group and therefore did not receive any vaccination

Baseline characteristics

Reporting groups	
Reporting group title	Menveo-Menveo Group
Reporting group description:	
Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.	
Reporting group title	Menactra-Menveo Group
Reporting group description:	
Healthy subjects,15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.	
Reporting group title	Naive Group
Reporting group description:	
Healthy subjects,15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.	

Reporting group values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group
Number of subjects	301	300	100
Age categorical Units: Subjects			
Adolescents	247	228	4
Adults	54	72	96
Age continuous Units: years			
arithmetic mean	17.1	17.9	38.8
standard deviation	± 3.66	± 4.54	± 10.47
Gender categorical Units: Subjects			
Female	144	156	68
Male	157	144	32
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	2	6	1
Asian	4	14	3
Black or African American	24	23	12
Native Hawaiian or other Pacific Islander	3	1	0
Unspecified	17	23	5
White	251	233	79

Reporting group values	Total		
Number of subjects	701		
Age categorical Units: Subjects			
Adolescents	479		
Adults	222		

Age continuous Units: years arithmetic mean standard deviation	- 		
Gender categorical Units: Subjects			
Female	368		
Male	333		
Race/Ethnicity, Customized Units: Subjects			
American Indian or Alaska Native	9		
Asian	21		
Black or African American	59		
Native Hawaiian or other Pacific Islander	4		
Unspecified	45		
White	563		

End points

End points reporting groups

Reporting group title	Menveo-Menveo Group
Reporting group description:	
Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.	
Reporting group title	Menactra-Menveo Group
Reporting group description:	
Healthy subjects,15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.	
Reporting group title	Naive Group
Reporting group description:	
Healthy subjects,15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.	
Subject analysis set title	pooled group (menveo-menveo and menactra-menveo)
Subject analysis set type	Per protocol
Subject analysis set description:	
Pooled subjects from both Menveo-Menveo and Menactra-Menveo Groups	

Primary: Percentages of subjects with human Serum Bactericidal Antibody (hSBA) seroresponse against Neisseria meningitidis serogroups A, C, W and Y.

End point title	Percentages of subjects with human Serum Bactericidal Antibody (hSBA) seroresponse against Neisseria meningitidis serogroups A, C, W and Y.
End point description:	
Seroresponse was defined as follows:for subjects with pre-vaccination hSBA titers< 4,postvaccination hSBA titers≥16;for subjects with pre-vaccination hSBA titers≥4,post vaccination hSBA titers of atleast 4 times the pre-vaccination titers.Criteria to demonstrate primary objectives:Immune response sufficiency was tested sequentially;first in the group of subjects who received primary vaccination with Menveo &,if met,also in group of subjects who received primary vaccination with Menactra.Immune response is considered sufficient if lower limit of the 1-sided 97.5% CI for percentage of subjects with hSBA seroresponse against serogroups A, C, W & Y is greater than 75%.Study is considered successful if immune response sufficiency is demonstrated atleast in group of subjects who received primary vaccination with Menveo.This outcome measure was assessed only on subjects from Menveo-Menveo & Menactra-Menveo groups.Data from pooled and Naive groups are presented as part of secondary objectives	
End point type	Primary
End point timeframe:	
At Day 29	

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	571
Units: Percentages of subjects				
number (confidence interval 95%)				
hSBA-Men A, Pre < 4 (N-246,234,85,480)	97.97 (95.32 to 99.34)	97.01 (93.93 to 98.79)	64.71 (53.59 to 74.77)	97.50 (95.67 to 98.70)

hSBA-Men A, Pre ≥ 4(N-43,48,8,91)	88.37 (74.92 to 96.11)	93.75 (82.8 to 98.69)	75.00 (34.91 to 96.81)	91.21 (83.41 to 96.13)
hSBA-Men A, Total seroresponse(N-289,282,93,571)	96.54 (93.73 to 98.33)	96.45 (93.58 to 98.29)	65.59 (55.02 to 75.14)	96.50 (94.64 to 97.85)
hSBA-Men C, Pre < 4(N-85,103,43,188)	100 (95.75 to 100)	100 (96.48 to 100)	55.81 (39.88 to 70.92)	100 (98.06 to 100)
hSBA-Men C, Pre ≥ 4(N-203,177,50,380)	93.6 (89.3 to 96.55)	93.79 (89.15 to 96.86)	58.00 (43.21 to 71.81)	93.68 (90.75 to 95.91)
hSBA-Men C, Total seroresponse(N-288,280,93,568)	95.49 (92.4 to 97.57)	96.07 (93.08 to 98.02)	56.99 (46.31 to 67.22)	95.77 (93.78 to 97.27)
hSBA-Men W, Pre < 4(N-52,58,33,110)	100 (93.15 to 100)	100 (93.84 to 100)	54.55 (36.35 to 71.89)	100 (96.70 to 100)
hSBA-Men W, Pre ≥ 4(N-237,223,59,460)	94.94 (91.32 to 97.36)	91.48 (87.01 to 94.79)	25.42 (14.98 to 38.44)	93.26 (90.57 to 95.38)
hSBA-Men W, Total seroresponse(N-289,281,92,570)	95.85 (92.86 to 97.84)	93.24 (89.64 to 95.88)	35.87 (26.13 to 46.54)	94.56 (92.37 to 96.28)
hSBA-Men Y, Pre < 4(N-115,123,54,238)	100 (96.84 to 100)	97.56 (93.04 to 99.49)	55.56 (41.40 to 69.08)	98.74 (96.36 to 99.74)
hSBA-Men Y, Pre ≥ 4(N-172,157,39,329)	94.77 (90.3 to 97.58)	91.72 (86.26 to 95.52)	46.15 (30.09 to 62.82)	93.31 (90.05 to 95.76)
hSBA-Men Y, Total seroresponse(N-287,280,93,567)	96.86 (94.13 to 98.56)	94.29 (90.89 to 96.7)	51.61 (41.01 to 62.11)	95.59 (93.56 to 97.13)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup A-day 29-Total seroresponse (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[1]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	30.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.76
upper limit	41.25

Notes:

[1] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Serogroup A-day 29-Total seroresponse (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group

Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[2]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	30.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.66
upper limit	41.17

Notes:

[2] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup A-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[3]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	30.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.89
upper limit	41.12

Notes:

[3] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup A- DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[4]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.15
upper limit	3.36

Notes:

[4] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Serogroup C-day 29-Total seroresponse (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[5]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	38.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.54
upper limit	48.9

Notes:

[5] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup C-day 29-Total seroresponse (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[6]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	39.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.16
upper limit	49.46

Notes:

[6] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Serogroup C-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[7]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	38.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.03
upper limit	49.06

Notes:

[7] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup C-DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[8]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	-0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.12
upper limit	2.92

Notes:

[8] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup W-day 29-Total seroresponse (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[9]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	59.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.49
upper limit	69.32

Notes:

[9] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup W-day 29-Total seroresponse (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[10]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	57.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.71
upper limit	66.88

Notes:

[10] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Serogroup W-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[11]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	58.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	48.32
upper limit	67.94

Notes:

[11] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup W-DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[12]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	2.61

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.17
upper limit	6.62

Notes:

[12] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13
Statistical analysis description:	
Serogroup Y-day 29-Total seroresponse (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[13]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	45.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	35.11
upper limit	55.47

Notes:

[13] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup Y-day 29-Total seroresponse (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[14]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	42.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.34
upper limit	53.04

Notes:

[14] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Serogroup Y-day 29-Total seroresponse (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[15]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	43.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.92
upper limit	54.14

Notes:

[15] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup Y- DAY 29 : Total seroresponse (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[16]
Method	Miettinen & Nurminen score method
Parameter estimate	Difference in percentages
Point estimate	2.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	6.3

Notes:

[16] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

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

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

End point description:

An AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom , or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product. An unsolicited adverse event is an adverse event that was not solicited using a subject diary and that was spontaneously communicated by a subject and/or parent(s)/legal guardian(s) who has signed the informed consent.

End point type	Secondary

End point timeframe:

Within 30 minutes after vaccination

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	301	300	100	601
Units: Participants				
Any Unsolicited AEs	0	8	1	8

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting solicited local and systemic AEs

End point title	Number of subjects reporting solicited local and systemic AEs

End point description:

Assessed solicited local symptoms were injection site pain, erythema, induration. Assessed solicited systemic symptoms were fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills and fever [defined and measured by a body temperature ≥37.5 degrees Celsius (ºC)]. Threshold for Erythema and Induration: Grade 0 (<25 mm), Any (>= 25 mm)

End point type	Secondary

End point timeframe:

From Day 1 (6 hours) through Day 7 after vaccination

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	296	296	97	592
Units: Participants				
Any Local symptom(N-296,296,97,592)	119	97	41	216
Any Systemic symptom(N-296,296,97,592)	162	148	35	310
Any Induration(N-286,286,92,592)	15	9	8	24
Any Erythema(N-286,287,92,573)	12	8	10	20
Any Pain(N-292,296,97,588)	114	96	40	210
Any Nausea(N-294,294,97,588)	48	44	13	92
Any Fatigue(N-295,296,97,591)	113	110	19	223
Any Myalgia(N-294,296,97,590)	55	54	15	109
Any Arthralgia(N-294,295,96,589)	44	38	13	82
Any Headache(N-294,295,97,589)	100	82	21	182
Any loss of apetite(N-294,296,97,590)	37	46	6	83
Any chills(N-294,295,97,589)	34	35	10	69
Fever(N-296,296,97,592)	2	5	0	7

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting other indicators of reactogenicity

End point title	Number of subjects reporting other indicators of reactogenicity

End point description:

Assessed indicators of reactogenicity were use of analgesics/antipyretics for prophylaxis, use of analgesics/antipyretics for treatment, body temperature (described as 0.5 °C increments from ≥ 36.0ºC)

End point type	Secondary

End point timeframe:

From Day 1 (6 hours) through Day 7 after vaccination

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	296	296	97	592
Units: Participants				
Analgesic/antipyretic-prophylaxis(N-294,295,96,589	13	15	5	28
Analgesic/antipyretic-treatment(N-293,295,96 ,588)	18	24	10	42
Body temp(36.0 - 36.4 ºC)(N-296,296,97,592)	68	57	16	125
Body temp (36.5 - 36.9 ºC)(N-296,296,97,592)	135	141	45	276
Body temp (37.0 - 37.4 ºC)(N-296,296,97,592)	83	77	33	160
Body temp (37.5 - 37.9 ºC)(N-296,296,97,592)	6	9	3	15
Body temp (38.0 - 38.4 ºC)(N-296,296,97,592)	1	2	0	3
Body temp (38.5 - 38.9 ºC)(N-296,296,97,592)	1	3	0	4
Body temp (39.0 - 39.4 ºC)(N-296,296,97,592)	0	0	0	0
Body temp (39.5 - 39.9 ºC)(N-296,296,97,592)	0	0	0	0
Body temp (>=40ºC)(N-296,296,97,592)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting all unsolicited AEs

End point title	Number of subjects reporting all unsolicited AEs

End point description:

An AE can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom , or disease temporally associated with the use of an investigational product, whether or not considered related to the investigational product. An unsolicited adverse event was an adverse event that was not solicited using a subject diary and that was spontaneously communicated by a subject and/or parent(s)/legal guardian(s) who has signed the informed consent.

End point type	Secondary

End point timeframe:

From Day 1 through Day 29 after vaccination

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	301	300	100	601
Units: Participants				
All unsolicited AEs	74	78	22	152

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting medically-attended AEs (MAAEs), AEs leading to withdrawal and serious AEs (SAEs)

End point title	Number of subjects reporting medically-attended AEs (MAAEs), AEs leading to withdrawal and serious AEs (SAEs)

End point description:

Medically attended AEs were defined as symptoms or illnesses requiring hospitalization, or emergency room visit, or visit to/by a health care provider. SAE was defined as any untoward medical occurrence that at any dose resulted in: death, was life-threatening, required or prolonged hospitalization, persistent or significant disability/incapacity, congenital anomaly/or birth defect, an important and significant medical event that might not have been immediately life threatening or resulting in death or hospitalization but, based upon appropriate medical judgment, might jeopardized the subject or might required intervention to prevent one of the other outcomes listed.

End point type	Secondary

End point timeframe:

From Day 1 through Day 181 (entire study period)

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	301	300	100	601
Units: Participants				
Any MAAEs	102	79	19	181
Any AEs leading to withdrawal	0	0	0	0
Any SAEs	3	2	3	5

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup A

End point title	Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup A

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥8 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At Day 1 (pre-vaccination), Day 4, Day 6 and Day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	572
Units: Percentages of subjects				
number (confidence interval 95%)				
hSBA-Men A ≥ 8, Day 1(N-289,282,93,571)	12.46 (8.88 to 16.83)	14.89 (10.95 to 19.59)	4.3 (1.18 to 10.65)	13.66 (10.95 to 16.75)
hSBA-Men A ≥ 8, Day 4(N-144,138,48,282)	11.11 (6.49 to 17.42)	13.04 (7.92 to 19.83)	4.17 (0.51 to 14.25)	12.06 (8.5 to 16.44)
hSBA-Men A ≥ 8, Day 6(N-146,140,44,286)	53.42 (44.99 to 61.71)	47.14 (38.66 to 55.75)	9.09 (2.53 to 21.67)	50.35 (44.4 to 56.29)
hSBA-Men A ≥ 8, Day 29(N-290,282,93,572)	98.62 (96.51 to 99.62)	98.94 (96.92 to 99.78)	70.97 (60.64 to 79.92)	98.78 (97.49 to 99.51)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[17]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	8.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	13.41

Notes:

[17] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[18]
Method	Miettinen & Nurminen score method
Parameter estimate	Between group differences in percentage
Point estimate	10.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.54
upper limit	16.14

Notes:

[18] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 1- (Pooled Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[19]
Method	Miettinen & Nurminen score method
Parameter estimate	Between group differences in percentage
Point estimate	9.36

Confidence interval	
level	95 %
sides	2-sided
lower limit	2.72
upper limit	13.58

Notes:

[19] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[20]
Method	Miettinen & Nurminen score method
Parameter estimate	Between group differences in percentage
Point estimate	-2.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.17
upper limit	3.24

Notes:

[20] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method.

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[21]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	6.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.57
upper limit	14.15

Notes:

[21] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group

Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[22]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	8.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	16.52

Notes:

[22] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[23]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	7.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.34
upper limit	13.48

Notes:

[23] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[24]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-1.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.84
upper limit	5.82

Notes:

[24] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[25]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	44.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.25
upper limit	54.6

Notes:

[25] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[26]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	38.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.93
upper limit	48.58

Notes:

[26] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[27]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	41.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.15
upper limit	49.72

Notes:

[27] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[28]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	6.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.31
upper limit	17.71

Notes:

[28] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[29]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	27.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.25
upper limit	37.65

Notes:

[29] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[30]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	27.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.6
upper limit	37.95

Notes:

[30] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[31]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	27.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.5
upper limit	37.76

Notes:

[31] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16
Statistical analysis description:	
Serogroup A- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[32]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-0.32

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.56
upper limit	1.86

Notes:

[32] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup C

End point title	Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup C

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥8 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	281	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men C ≥ 8, Day 1(N-288,281,93,569)	61.11 (55.22 to 66.77)	53.74 (47.72 to 59.68)	33.33 (23.89 to 43.87)	57.47 (53.29 to 61.57)
hSBA-Men C ≥ 8, Day 4 (N-144,138,48,282)	70.83 (62.68 to 78.1)	60.14 (51.47 to 68.38)	43.75 (29.48 to 58.82)	65.6 (59.74 to 71.13)
hSBA-Men C ≥ 8, Day 6(N-145,139,44,284)	87.59 (81.09 to 92.47)	92.09 (86.28 to 95.98)	43.18 (28.35 to 58.97)	89.79 (85.66 to 93.05)
hSBA-Men C ≥ 8, Day 29(N-290,281,93,571)	100 (98.74 to 100)	99.64 (98.03 to 99.99)	87.1 (78.55 to 93.15)	99.82 (99.03 to 100)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[33]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	27.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.23
upper limit	38.27

Notes:

[33] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[34]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	20.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.78
upper limit	31.03

Notes:

[34] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[35]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	24.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.28
upper limit	33.86

Notes:

[35] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[36]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	7.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	15.42

Notes:

[36] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[37]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	27.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.04
upper limit	42.14

Notes:

[37] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[38]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	16.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.04
upper limit	31.9

Notes:

[38] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[39]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	21.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.73
upper limit	36.11

Notes:

[39] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[40]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	10.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	21.6

Notes:

[40] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[41]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	44.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.65
upper limit	58.93

Notes:

[41] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[42]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	48.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.45
upper limit	63.13

Notes:

[42] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[43]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	46.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.52
upper limit	60.59

Notes:

[43] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[44]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.84
upper limit	2.69

Notes:

[44] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[45]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.53
upper limit	21.22

Notes:

[45] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[46]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	12.55

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	20.89

Notes:

[46] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[47]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	12.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.34
upper limit	21.05

Notes:

[47] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup C- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[48]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	1.99

Notes:

[48] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentage of subjects with hSBA titer ≥8 against N. meningitidis serogroup W

End point title	Percentage of subjects with hSBA titer ≥8 against N. meningitidis serogroup W

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥8 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men W ≥ 8, Day 1(N-289,282,93,571)	75.43 (70.05 to 80.29)	76.95 (71.59 to 81.74)	61.29 (50.62 to 71.22)	76.18 (72.47 to 79.62)
hSBA-Men W ≥ 8, Day 4(144,138,48,282)	81.94 (74.67 to 87.85)	82.61 (75.24 to 88.53)	62.5 (47.35 to 76.05)	82.27 (77.3 to 86.54)
hSBA-Men W ≥ 8, Day 6(N-146,140,44,286)	93.84 (88.62 to 97.14)	97.86 (93.87 to 99.56)	63.64 (47.77 to 77.59)	95.8 (92.79 to 97.81)
hSBA-Men W ≥ 8, Day 29(N-290,281,92,571)	100 (98.74 to 100)	100 (98.7 to 100)	84.78 (75.79 to 91.42)	100 (99.36 to 100)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[49]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	14.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.46
upper limit	25.39

Notes:

[49] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group

Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[50]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	15.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	5
upper limit	26.89

Notes:

[50] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[51]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	14.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.91
upper limit	25.62

Notes:

[51] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[52]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-1.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.51
upper limit	5.5

Notes:

[52] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[53]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.25
upper limit	34.83

Notes:

[53] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[54]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	20.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.88
upper limit	35.5

Notes:

[54] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[55]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.53
upper limit	34.58

Notes:

[55] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[56]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.67
upper limit	8.4

Notes:

[56] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[57]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	30.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.78
upper limit	45.45

Notes:

[57] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[58]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	34.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.29
upper limit	49.2

Notes:

[58] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[59]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	32.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.3
upper limit	47.13

Notes:

[59] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[60]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-4.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.45
upper limit	0.74

Notes:

[60] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[61]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	15.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.28
upper limit	23.95

Notes:

[61] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[62]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	15.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.28
upper limit	23.95

Notes:

[62] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[63]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	15.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.28
upper limit	23.94

Notes:

[63] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup W- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[64]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.31
upper limit	1.35

Notes:

[64] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup Y

End point title	Percentages of subjects with hSBA titer ≥8 against N. meningitidis serogroup Y

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥8 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	281	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men Y ≥ 8, Day 1(N-287,281,93,568)	54.01 (48.05 to 59.88)	46.98 (41.02 to 52.99)	32.26 (22.93 to 42.75)	50.53 (46.33 to 54.72)
hSBA-Men Y ≥ 8, Day 4(N-143,138,48,281)	55.24 (46.71 to 63.56)	55.8 (47.1 to 64.24)	33.33 (20.4 to 48.41)	55.52 (49.5 to 61.42)
hSBA-Men Y ≥ 8, Day 6(N-145,140,44,285)	85.52 (78.72 to 90.81)	87.86 (81.27 to 92.76)	45.45 (30.39 to 61.15)	86.67 (82.16 to 90.39)
hSBA-Men Y ≥ 8, Day 29(N-290,281,93,571)	100 (98.74 to 100)	99.64 (98.03 to 99.99)	77.42 (67.58 to 85.45)	99.82 (99.03 to 100)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[65]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	21.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.19
upper limit	32.25

Notes:

[65] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[66]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	14.72

Confidence interval	
level	95 %
sides	2-sided
lower limit	3.15
upper limit	25.29

Notes:

[66] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[67]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	18.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.44
upper limit	27.92

Notes:

[67] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[68]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	7.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	15.17

Notes:

[68] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[69]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	21.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.57
upper limit	36.37

Notes:

[69] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[70]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.05
upper limit	37

Notes:

[70] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[71]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.89
upper limit	35.38

Notes:

[71] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[72]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-0.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.11
upper limit	11.03

Notes:

[72] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[73]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	40.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.26
upper limit	54.95

Notes:

[73] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[74]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	42.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	26.71
upper limit	57.17

Notes:

[74] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[75]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	41.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.12
upper limit	55.55

Notes:

[75] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[76]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-2.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.41
upper limit	5.73

Notes:

[76] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[77]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.26
upper limit	32.08

Notes:

[77] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[78]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.86
upper limit	31.74

Notes:

[78] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[79]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.08
upper limit	31.9

Notes:

[79] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup Y- hSBA titer ≥8-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[80]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.96
upper limit	1.99

Notes:

[80] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup A

End point title	Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup A

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥16 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	572
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men A ≥ 16, Day 1(N-289,282,93,571)	8.3 (5.39 to 12.1)	9.57 (6.4 to 13.62)	1.08 (0.03 to 5.85)	8.93 (6.72 to 11.58)
hSBA-Men A ≥ 16, Day 4(N-144,138,48,282)	8.33 (4.38 to 14.1)	8.7 (4.57 to 14.7)	2.08 (0.05 to 11.07)	8.51 (5.53 to 12.4)
hSBA-Men A ≥ 16, Day 6(N-146,140,44,286)	45.89 (37.62 to 54.33)	41.43 (33.17 to 50.05)	4.55 (0.56 to 15.47)	43.71 (37.87 to 49.67)
hSBA-Men A ≥ 16, Day 29(N-290,282,93,572)	98.28 (96.02 to 99.44)	97.52 (94.95 to 99)	66.67 (56.13 to 76.11)	97.9 (96.36 to 98.91)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[81]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	7.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.08
upper limit	11.23

Notes:

[81] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[82]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	8.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.28
upper limit	12.74

Notes:

[82] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[83]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	7.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.87
upper limit	10.78

Notes:

[83] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[84]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.1
upper limit	3.49

Notes:

[84] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[85]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	6.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.04
upper limit	12.44

Notes:

[85] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[86]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	6.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.71
upper limit	13.01

Notes:

[86] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[87]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	6.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.66
upper limit	10.9

Notes:

[87] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[88]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-0.36

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.27
upper limit	6.43

Notes:

[88] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[89]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	41.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.85
upper limit	50.63

Notes:

[89] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[90]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	36.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.39
upper limit	46.34

Notes:

[90] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[91]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	39.16
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.61
upper limit	46.33

Notes:

[91] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[92]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	4.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.04
upper limit	15.83

Notes:

[92] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[93]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	31.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.68
upper limit	41.79

Notes:

[93] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[94]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	30.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.85
upper limit	41.08

Notes:

[94] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[95]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	31.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.39
upper limit	41.38

Notes:

[95] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16
Statistical analysis description:	
Serogroup A- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[96]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.81
upper limit	3.52

Notes:

[96] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup C

End point title	Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup C

End point description:

Analysis was performed on per protocol set for immunogenicity, which included all randomized subjects who had no protocol deviations and were not excluded due to other reasons defined prior to unblinding/analysis, who received study vaccination and provided evaluable serum samples at each time point, with result available for at least 1 serogroup

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	281	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men C ≥ 16, Day 1(N-288,281,93,569)	47.22 (41.34 to 53.16)	38.08 (32.38 to 44.04)	17.2 (10.17 to 26.43)	42.71 (38.6 to 46.89)
hSBA-Men C ≥ 16, Day 4(N-144,138,48,282)	54.17 (45.67 to 62.49)	44.93 (36.46 to 53.62)	29.17 (16.95 to 44.06)	49.65 (43.66 to 55.64)
hSBA-Men C ≥ 16, Day 6(N-145,139,44,284)	82.07 (74.84 to 87.94)	81.29 (73.81 to 87.4)	31.82 (18.61 to 47.58)	81.69 (76.69 to 86.01)
hSBA-Men C ≥ 16, Day 29(N-290,281,93,571)	99.66 (98.09 to 99.99)	99.64 (98.03 to 99.99)	69.89 (59.5 to 78.97)	99.65 (98.74 to 99.96)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[97]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	30.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.55
upper limit	38.83

Notes:

[97] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[98]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	20.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.48
upper limit	29.69

Notes:

[98] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[99]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	25.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.79
upper limit	33.21

Notes:

[99] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[100]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	9.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	17.16

Notes:

[100] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[101]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	25
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.82
upper limit	38.9

Notes:

[101] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[102]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	15.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.44
upper limit	29.86

Notes:

[102] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[103]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	20.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.32
upper limit	33.08

Notes:

[103] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[104]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	9.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.45
upper limit	20.68

Notes:

[104] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[105]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	50.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.09
upper limit	63.67

Notes:

[105] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[106]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	49.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.21
upper limit	63.01

Notes:

[106] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[107]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	49.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.42
upper limit	62.6

Notes:

[107] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[108]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	9.92

Notes:

[108] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[109]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	29.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.34
upper limit	39.75

Notes:

[109] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[110]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	29.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	21.32
upper limit	39.74

Notes:

[110] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[111]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	29.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.35
upper limit	39.73

Notes:

[111] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup C- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[112]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	1.67

Notes:

[112] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup W

End point title	Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup W

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥16 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination), day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men W ≥ 16, Day 1(N-289,282,93,571)	65.74 (59.96 to 71.2)	66.31 (60.47 to 71.81)	48.39 (37.89 to 58.99)	66.02 (61.98 to 69.91)
hSBA-Men W ≥ 16, Day 4(N-144,138,48,282)	68.75 (60.5 to 76.21)	76.81 (68.87 to 83.57)	54.17 (39.17 to 68.63)	72.7 (67.1 to 77.81)
hSBA-Men W ≥ 16, Day 6(N-146,140,44,286)	89.04 (82.81 to 93.6)	92.14 (86.38 to 96.01)	50 (34.56 to 65.44)	90.56 (86.56 to 93.69)
hSBA-Men W ≥ 16, Day 29(N-290,281,92,571)	100 (98.74 to 100)	100 (98.7 to 100)	80.43 (70.85 to 87.97)	100 (99.36 to 100)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[113]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	17.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.85
upper limit	28.67

Notes:

[113] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group

Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[114]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	17.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.39
upper limit	29.25

Notes:

[114] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[115]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	17.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.85
upper limit	28.28

Notes:

[115] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[116]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-0.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.32
upper limit	7.2

Notes:

[116] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[117]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	14.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.98
upper limit	30.38

Notes:

[117] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[118]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	22.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.3
upper limit	38.16

Notes:

[118] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[119]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	18.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.14
upper limit	33.37

Notes:

[119] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[120]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-8.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.34
upper limit	2.38

Notes:

[120] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[121]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	39.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.76
upper limit	54.07

Notes:

[121] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[122]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	42.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.08
upper limit	56.98

Notes:

[122] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[123]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	40.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.91
upper limit	55.15

Notes:

[123] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[124]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	-3.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	3.89

Notes:

[124] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[125]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.74
upper limit	28.83

Notes:

[125] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[126]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.74
upper limit	28.83

Notes:

[126] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)

Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[127]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.75
upper limit	28.83

Notes:

[127] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup W- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[128]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.31
upper limit	1.35

Notes:

[128] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup Y

End point title	Percentages of subjects with hSBA titer ≥16 against N. meningitidis serogroup Y

End point description:

For each study group and in the pooled group, percentages of subjects with hSBA titer ≥16 and associated two-sided 95%CIs were calculated.

End point type	Secondary

End point timeframe:

At day 1(pre-vaccination) , day 4, day 6 and day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	281	93	571
Units: Percentage of subjects				
number (confidence interval 95%)				
hSBA-Men Y ≥ 16, Day 1(N-287,281,93,568)	39.02 (33.35 to 44.93)	34.88 (29.31 to 40.76)	17.2 (10.17 to 26.43)	36.97 (32.99 to 41.09)
hSBA-Men Y ≥ 16, Day 4(N-143,138,48,281)	39.16 (31.11 to 47.67)	39.13 (30.94 to 47.8)	20.83 (10.47 to 34.99)	39.15 (33.4 to 45.12)
hSBA-Men Y ≥ 16, Day 6(N-145,140,44,285)	80.69 (73.31 to 86.77)	80 (72.41 to 86.28)	31.82 (18.61 to 47.58)	80.35 (75.26 to 84.8)
hSBA-Men Y ≥ 16, Day 29(N-290,281,93,571)	100 (98.74 to 100)	98.58 (96.4 to 99.61)	64.52 (53.91 to 74.17)	99.3 (98.22 to 99.81)

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[129]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	21.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.44
upper limit	30.6

Notes:

[129] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 1- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[130]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	17.67

Confidence interval	
level	95 %
sides	2-sided
lower limit	7.34
upper limit	26.43

Notes:

[130] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 1- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[131]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	19.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.09
upper limit	27.43

Notes:

[131] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 1- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[132]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	4.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.8
upper limit	12.04

Notes:

[132] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[133]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	18.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.92
upper limit	30.99

Notes:

[133] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 4- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[134]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.83
upper limit	31.06

Notes:

[134] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 4- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[135]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	18.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.83
upper limit	29.39

Notes:

[135] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 4- (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[136]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.35
upper limit	11.39

Notes:

[136] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Naive)	
Comparison groups	Naive Group v Menveo-Menveo Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[137]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	48.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.64
upper limit	62.38

Notes:

[137] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 6- (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[138]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	48.18

Confidence interval	
level	95 %
sides	2-sided
lower limit	31.87
upper limit	61.79

Notes:

[138] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 6- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[139]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	48.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.04
upper limit	61.31

Notes:

[139] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 6- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[140]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.6
upper limit	10.04

Notes:

[140] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Naive)

Comparison groups	Naive Group v Menveo-Menveo Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[141]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	35.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.5
upper limit	45.62

Notes:

[141] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 29- (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	other[142]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	34.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.94
upper limit	44.28

Notes:

[142] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 29- (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[143]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	34.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.78
upper limit	44.93

Notes:

[143] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16

Statistical analysis description:

Serogroup Y- hSBA titer ≥16-Vaccine comparison at Day 29- (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menactra-Menveo Group v Menveo-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[144]
Method	Miettinen & Nurminen score method
Parameter estimate	Between groups differences in percentage
Point estimate	1.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	3.6

Notes:

[144] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: Percentages of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y

End point title	Percentages of subjects with hSBA seroresponse against N. meningitidis serogroups A, C, W and Y

End point description:

Seroresponse is defined for this study as follows: For subjects with pre-vaccination titers <4, postvaccination titers ≥ 16; for subjects with pre-vaccination titers ≥4, post vaccination titers at least 4 times the pre-vaccination titers.

End point type	Secondary

End point timeframe:

At Day 4 and Day 6

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	289	282	93	571
Units: Percentages of subjects				
number (confidence interval 95%)				
hSBA-Men A, Pre < 4, Day 4(N-123,117,45,240)	0.81 (0.02 to 4.45)	2.56 (0.53 to 7.31)	0 (0 to 7.87)	1.67 (0.46 to 4.21)
hSBA-Men A, Pre ≥ 4, Day 4(N-21,21,3,42)	4.76 (0.12 to 23.82)	0 (0 to 16.11)	0 (0 to 70.76)	2.38 (0.06 to 12.57)
hSBA-Men A,Total seroresponse,Day 4(144,138,48,282	1.39 (0.17 to 4.93)	2.17 (0.45 to 6.22)	0 (0 to 7.4)	1.77 (0.58 to 4.09)
hSBA-Men A, Pre < 4, Day 6(N-123,113,39,236)	39.84 (31.12 to 49.05)	33.63 (25.01 to 43.12)	2.56 (0.06 to 13.48)	36.86 (30.7 to 43.37)

hSBA-Men A, Pre ≥ 4, Day 6(N-22,27,5,49)	36.36 (17.2 to 59.34)	22.22 (8.62 to 42.26)	20 (0.51 to 71.64)	28.57 (16.58 to 43.26)
hSBA-Men A,Total seroresponse,Day 6(145,140,44,285	39.31 (31.31 to 47.76)	31.43 (23.85 to 39.81)	4.55 (0.56 to 15.47)	35.44 (29.89 to 41.3)
hSBA-Men C, Pre < 4, Day 4(N-36,51,20,87)	0 (0 to 9.74)	9.8 (3.26 to 21.41)	5 (0.13 to 24.87)	5.75 (1.89 to 12.9)
hSBA-Men C, Pre ≥ 4, Day 4(N-107,86,28,193)	3.74 (1.03 to 9.3)	8.14 (3.34 to 16.05)	7.14 (0.88 to 23.5)	5.7 (2.88 to 9.97)
hSBA-Men C,Total seroresponse,Day 4(143,137,48,280	2.8 (0.77 to 7.01)	8.76 (4.61 to 14.8)	6.25 (1.31 to 17.2)	5.71 (3.3 to 9.11)
hSBA-Men C, Pre < 4, Day 6(N-49,51,23,100)	65.31 (50.36 to 78.33)	64.71 (50.07 to 77.57)	13.04 (2.78 to 33.59)	65 (54.82 to 74.27)
hSBA-Men C, Pre ≥ 4, Day 6(N-95,88,21,183)	44.21 (34.02 to 54.77)	38.64 (28.44 to 49.62)	9.52 (1.17 to 30.38)	41.53 (34.31 to 49.03)
hSBA-Men C,Total seroresponse,Day 6(144,139,44,283	51.39 (42.92 to 59.8)	48.2 (39.65 to 56.83)	11.36 (3.79 to 24.56)	49.82 (43.85 to 55.8)
hSBA-Men W, Pre < 4, Day 4(N-21,30,17,51)	9.52 (1.17 to 30.38)	30 (14.73 to 49.4)	11.76 (1.46 to 36.44)	21.57 (11.29 to 35.32)
hSBA-Men W, Pre ≥ 4, Day 4(N-123,108,31,231)	1.63 (0.2 to 5.75)	4.63 (1.52 to 10.47)	3.23 (0.08 to 16.7)	3.03 (1.23 to 6.14)
hSBA-Men W,Total seroresponse,Day 4(144,138,48,282	2.78 (0.76 to 6.96)	10.14 (5.66 to 16.44)	6.25 (1.31 to 17.2)	6.38 (3.83 to 9.9)
hSBA-Men W, Pre < 4, Day 6(N-31,28,16,59)	64.52 (45.37 to 80.77)	75 (55.13 to 89.31)	25 (7.27 to 52.38)	69.49 (56.13 to 80.81)
hSBA-Men W, Pre ≥ 4, Day 6(N-114,112,28,226)	46.49 (37.1 to 56.07)	42.86 (33.55 to 52.55)	3.57 (0.09 to 18.35)	44.69 (38.09 to 51.43)
hSBA-Men W,Total seroresponse,Day 6(145,140,44,285	50.34 (41.93 to 58.75)	49.29 (40.74 to 57.86)	11.36 (3.79 to 24.56)	49.82 (43.87 to 55.78)
hSBA-Men Y, Pre < 4, Day 4(N-62,60,27,122)	8.06 (2.67 to 17.83)	6.67 (1.85 to 16.2)	0 (0 to 12.77)	7.38 (3.43 to 13.54)
hSBA-Men Y, Pre ≥ 4, Day 4(N-80,77,21,157)	7.5 (2.8 to 15.61)	2.6 (0.32 to 9.07)	0 (0 to 16.11)	5.1 (2.23 to 9.79)
hSBA-Men Y,Total seroresponse,Day 4(142,137,48,279	7.75 (3.93 to 13.44)	4.38 (1.62 to 9.29)	0 (0 to 7.4)	6.09 (3.59 to 9.58)
hSBA-Men Y, Pre < 4, Day 6(N-52,62,27,114)	63.46 (48.96 to 76.38)	75.81 (63.26 to 85.78)	11.11 (2.35 to 29.16)	70.18 (60.89 to 78.38)
hSBA-Men Y, Pre ≥ 4, Day 6(N-91,78,17,169)	40.66 (30.48 to 51.47)	42.31 (31.19 to 54.02)	5.88 (0.15 to 28.69)	41.42 (33.91 to 49.24)
hSBA-Men Y,Total seroresponse,Day 6(143,140,44,283	48.95 (40.51 to 57.44)	57.14 (48.51 to 65.47)	9.09 (2.53 to 21.67)	53 (47.01 to 58.94)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup A- Day 4- Total seroresponse (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[145]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	1.39

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.08
upper limit	4.94

Notes:

[145] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 2
Statistical analysis description:	
Serogroup A- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[146]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	2.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.32
upper limit	6.21

Notes:

[146] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 3
Statistical analysis description:	
Serogroup A- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[147]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.68
upper limit	4.09

Notes:

[147] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Serogroup A- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group

Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[148]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.98
upper limit	3.01

Notes:

[148] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

Serogroup A- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[149]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	34.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.38
upper limit	44.07

Notes:

[149] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 6

Statistical analysis description:

Serogroup A- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[150]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	26.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.67
upper limit	36.13

Notes:

[150] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Serogroup A- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[151]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	30.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.42
upper limit	37.97

Notes:

[151] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Serogroup A- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[152]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	7.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.25
upper limit	18.81

Notes:

[152] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Serogroup C- Day 4-Total seroresponse- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[153]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-3.45

Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.26
upper limit	2.35

Notes:

[153] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 10
Statistical analysis description:	
Serogroup C- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[154]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	9.98

Notes:

[154] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 11
Statistical analysis description:	
Serogroup C- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[155]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-0.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.35
upper limit	4.9

Notes:

[155] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup C- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group

Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[156]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-5.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.25
upper limit	-0.57

Notes:

[156] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 13

Statistical analysis description:

Serogroup C- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[157]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	40.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.37
upper limit	50.92

Notes:

[157] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 14

Statistical analysis description:

Serogroup C- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[158]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	36.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.14
upper limit	47.9

Notes:

[158] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Serogroup C- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[159]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	38.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.79
upper limit	47.57

Notes:

[159] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 16
Statistical analysis description:	
Serogroup C- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[160]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	3.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.44
upper limit	14.73

Notes:

[160] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 17
Statistical analysis description:	
Serogroup W- Day 4-Total seroresponse- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[161]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-3.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.28
upper limit	2.31

Notes:

[161] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

Serogroup W- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[162]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	3.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.4
upper limit	11.6

Notes:

[162] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

Serogroup W- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[163]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	0.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.7
upper limit	5.66

Notes:

[163] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 20

Statistical analysis description:

Serogroup W- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group

Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[164]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-7.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.89
upper limit	-1.8

Notes:

[164] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 21

Statistical analysis description:

Serogroup W- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[165]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	38.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.35
upper limit	49.88

Notes:

[165] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 22

Statistical analysis description:

Serogroup W- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[166]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	37.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.23
upper limit	48.95

Notes:

[166] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 23
Statistical analysis description:	
Serogroup W- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[167]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	38.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.8
upper limit	47.56

Notes:

[167] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 24
Statistical analysis description:	
Serogroup W- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[168]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.51
upper limit	12.6

Notes:

[168] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 25
Statistical analysis description:	
Serogroup Y- Day 4-Total seroresponse- (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[169]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	7.75

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	13.36

Notes:

[169] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 26
Statistical analysis description:	
Serogroup Y- Day 4-Total seroresponse - (Menactra-Menveo vs. Naive)	
Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[170]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	4.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.15
upper limit	9.24

Notes:

[170] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 27
Statistical analysis description:	
Serogroup Y- Day 4-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[171]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	6.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.41
upper limit	9.55

Notes:

[171] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 28
Statistical analysis description:	
Serogroup Y- Day 4-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group

Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[172]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	3.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.48
upper limit	9.54

Notes:

[172] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 29

Statistical analysis description:

Serogroup Y- Day 6-Total seroresponse- (Menveo-Menveo vs. Naive)

Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	382
Analysis specification	Pre-specified
Analysis type	other[173]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	39.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	25.76
upper limit	50.29

Notes:

[173] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 30

Statistical analysis description:

Serogroup Y- Day 6-Total seroresponse - (Menactra-Menveo vs. Naive)

Comparison groups	Menactra-Menveo Group v Naive Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[174]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	48.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.89
upper limit	58.34

Notes:

[174] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 31
Statistical analysis description:	
Serogroup Y- Day 6-Total seroresponse - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	664
Analysis specification	Pre-specified
Analysis type	other[175]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	43.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.79
upper limit	52.37

Notes:

[175] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Statistical analysis title	Statistical analysis 32
Statistical analysis description:	
Serogroup Y- Day 6-Total seroresponse - (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	571
Analysis specification	Pre-specified
Analysis type	other[176]
Method	Miettinen & Nurminen score method
Parameter estimate	Differences in percentage
Point estimate	-8.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.61
upper limit	3.45

Notes:

[176] - Differences in percentages and associated 95% CIs between study groups were calculated using the Miettinen & Nurminen score method

Secondary: hSBA Geometric Mean Titers (GMTs) against N. meningitidis serogroup A, C, W and Y.

End point title	hSBA Geometric Mean Titers (GMTs) against N. meningitidis serogroup A, C, W and Y.

End point description:

For each N. meningitidis serogroup A, C, W and Y, unadjusted GMTs were calculated, with their associated two-sided 95% Confidence Interval.

End point type	Secondary

End point timeframe:

At Day 1 (pre-vaccination), Day 4, Day 6 and Day 29

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	290	282	93	572
Units: Titers				
geometric mean (confidence interval 95%)				
hSBA-Men A, Day 1(N-289,282,93,571)	2.81 (2.54 to 3.11)	2.95 (2.67 to 3.27)	2.27 (1.9 to 2.71)	2.88 (2.68 to 3.09)
hSBA-Men A, Day 4(N-144,138,48,282)	2.83 (2.43 to 3.29)	3 (2.57 to 3.51)	2.25 (1.73 to 2.93)	2.91 (2.61 to 3.25)
hSBA-Men A, Day 6(N-146,140,44,286)	12.87 (9.63 to 17.19)	10.17 (7.57 to 13.66)	2.48 (1.46 to 4.2)	11.47 (9.32 to 14.1)
hSBA-Men A, Day 29(N-290,282,93,572)	210.1 (181.07 to 243.78)	236.69 (203.56 to 275.2)	32.11 (24.7 to 41.76)	222.81 (200.43 to 247.7)
hSBA-Men C, Day 1(N-288,281,93,569)	16.11 (13.28 to 19.54)	10.72 (8.82 to 13.03)	5.06 (3.6 to 7.1)	13.17 (11.48 to 15.12)
hSBA-Men C, Day 4(N-144,138,48,282)	22.96 (17.31 to 30.45)	14.29 (10.71 to 19.07)	6.69 (4.1 to 10.9)	18.21 (14.86 to 22.31)
hSBA-Men C, Day 6(N-145,139,44,284)	92.27 (68.91 to 123.56)	90.06 (66.84 to 121.35)	6.71 (3.95 to 11.4)	91.18 (74.04 to 112.3)
hSBA-Men C, Day 29(N-290,281,93,571)	1159.93 (977.33 to 1376.63)	1057.66 (888.74 to 1258.68)	59.7 (44.12 to 80.78)	1108.42 (981.09 to 1252.27)
hSBA-Men W, Day 1(N-289,282,93,571)	22.07 (18.54 to 26.29)	23.46 (19.66 to 28)	12.21 (8.98 to 16.62)	22.75 (20.09 to 25.76)
hSBA-Men W, Day 4(N-144,138,48,282)	25.9 (20.13 to 33.32)	33.87 (26.18 to 43.82)	13.8 (8.92 to 21.35)	29.53 (24.66 to 35.37)
hSBA-Men W, Day 6(N-146,140,44,286)	112.49 (86.26 to 146.71)	143.75 (109.61 to 188.54)	15.98 (9.85 to 25.93)	126.84 (104.9 to 153.37)
hSBA-Men W, Day 29(N-290,281,92,571)	1394.65 (1176.59 to 1653.11)	1883.96 (1585.12 to 2239.15)	55.31 (40.9 to 74.8)	1617.11 (1431.93 to 1826.23)
hSBA-Men Y, Day 1(N-287,281,93,568)	9.24 (7.81 to 10.94)	8.22 (6.93 to 9.75)	4.56 (3.39 to 6.13)	8.72 (7.74 to 9.83)
hSBA-Men Y, Day 4(N-143,138,48,281)	10.87 (8.26 to 14.32)	12.12 (9.16 to 16.04)	4.63 (2.88 to 7.44)	11.47 (9.43 to 13.95)
hSBA-Men Y, Day 6(N-145,140,44,285)	63.3 (47.73 to 83.95)	61.56 (46.18 to 82.05)	6.44 (3.86 to 10.76)	62.44 (51.06 to 76.34)
hSBA-Men Y, Day 29(N-290,281,93,571)	1066.66 (900.67 to 1263.25)	1007.62 (848.53 to 1196.54)	37.4 (27.75 to 50.42)	1037.19 (919.46 to 1169.98)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 4(Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[177]
Parameter estimate	Between group GMT ratios
Point estimate	1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.93
upper limit	1.7

Notes:

[177] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Serogroup A-Vaccine comparison at day 4(Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[178]
Parameter estimate	Between group GMT ratios
Point estimate	1.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	1.82

Notes:

[178] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Serogroup A-Vaccine comparison at day 4(Pooled Menveo-Menveo and Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[179]
Parameter estimate	Between group GMT ratios
Point estimate	1.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.97
upper limit	1.72

Notes:

[179] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 4
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[180]
Parameter estimate	Between group GMT ratios
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.17

Notes:

[180] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 5
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[181]
Parameter estimate	Between group GMT ratios
Point estimate	5.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.84
upper limit	9.47

Notes:

[181] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 6
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[182]
Parameter estimate	Between group GMT ratios
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.24
upper limit	7.5

Notes:

[182] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 7
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[183]
Parameter estimate	Between group GMT ratios
Point estimate	4.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.62
upper limit	8.15

Notes:

[183] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 8
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[184]
Parameter estimate	Between group GMT ratios
Point estimate	1.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.91

Notes:

[184] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 9
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[185]
Parameter estimate	Between group GMT ratios
Point estimate	6.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.84
upper limit	8.85

Notes:

[185] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 10

Statistical analysis description:

Serogroup A-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[186]
Parameter estimate	Between group GMT ratios
Point estimate	7.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.44
upper limit	9.98

Notes:

[186] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 11

Statistical analysis description:

Serogroup A-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[187]
Parameter estimate	Between group GMT ratios
Point estimate	6.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.23
upper limit	9.21

Notes:

[187] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 12
Statistical analysis description:	
Serogroup A-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[188]
Parameter estimate	Between group GMT ratios
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.1

Notes:

[188] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 13
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[189]
Parameter estimate	between group GMT ratios
Point estimate	3.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.95
upper limit	6.04

Notes:

[189] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 14
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[190]
Parameter estimate	Between group GMT ratios
Point estimate	2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.21
upper limit	3.77

Notes:

[190] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 15
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[191]
Parameter estimate	Between group GMT ratios
Point estimate	2.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.6
upper limit	4.64

Notes:

[191] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 16
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[192]
Parameter estimate	Between group GMT ratios
Point estimate	1.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.07
upper limit	2.4

Notes:

[192] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 17
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[193]
Parameter estimate	Between group GMT ratios
Point estimate	13.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.51
upper limit	25.19

Notes:

[193] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 18

Statistical analysis description:

Serogroup C-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[194]
Parameter estimate	Between group GMT ratios
Point estimate	13.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.31
upper limit	24.66

Notes:

[194] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 19

Statistical analysis description:

Serogroup C-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[195]
Parameter estimate	Between group GMT ratios
Point estimate	13.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.7
upper limit	24

Notes:

[195] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 20
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[196]
Parameter estimate	Between group GMT ratios
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.67
upper limit	1.56

Notes:

[196] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 21
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[197]
Parameter estimate	Between group GMT ratios
Point estimate	19.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.73
upper limit	27.51

Notes:

[197] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 22
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[198]
Parameter estimate	Between group GMT ratios
Point estimate	17.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.5
upper limit	25.12

Notes:

[198] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 23
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[199]
Parameter estimate	Between group GMT ratios
Point estimate	18.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.4
upper limit	25.73

Notes:

[199] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 24
Statistical analysis description:	
Serogroup C-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[200]
Parameter estimate	Between group GMT ratios
Point estimate	1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.4

Notes:

[200] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 25
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[201]
Parameter estimate	Between group GMT ratios
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	3.11

Notes:

[201] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 26

Statistical analysis description:

Serogroup W-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[202]
Parameter estimate	Between group GMT ratios
Point estimate	2.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.48
upper limit	4.08

Notes:

[202] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 27

Statistical analysis description:

Serogroup W-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[203]
Parameter estimate	Between group GMT ratios
Point estimate	2.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.33
upper limit	3.44

Notes:

[203] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 28
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[204]
Parameter estimate	Between group GMT ratios
Point estimate	0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.1

Notes:

[204] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 29
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[205]
Parameter estimate	Between group GMT ratios
Point estimate	7.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.05
upper limit	12.22

Notes:

[205] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 30
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[206]
Parameter estimate	Between group GMT ratios
Point estimate	8.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.16
upper limit	15.66

Notes:

[206] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 31
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[207]
Parameter estimate	Between group GMT ratios
Point estimate	7.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.72
upper limit	13.35

Notes:

[207] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 32
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[208]
Parameter estimate	Between group GMT ratios
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	1.14

Notes:

[208] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 33
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[209]
Parameter estimate	Between group GMT ratios
Point estimate	25.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.83
upper limit	35.65

Notes:

[209] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 34

Statistical analysis description:

Serogroup W-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[210]
Parameter estimate	Between group GMT ratios
Point estimate	34.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.06
upper limit	48.23

Notes:

[210] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 35

Statistical analysis description:

Serogroup W-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[211]
Parameter estimate	Between group GMT ratios
Point estimate	29.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.09
upper limit	40.52

Notes:

[211] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 36
Statistical analysis description:	
Serogroup W-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[212]
Parameter estimate	Between group GMT ratios
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.94

Notes:

[212] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 37
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 4 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[213]
Parameter estimate	Between group GMT ratios
Point estimate	2.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.36
upper limit	4.07

Notes:

[213] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 38
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 4 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[214]
Parameter estimate	Between group GMT ratios
Point estimate	2.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	4.54

Notes:

[214] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 39
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 4 - (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)	
Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[215]
Parameter estimate	Between group GMT ratios
Point estimate	2.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.48
upper limit	4.14

Notes:

[215] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 40
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 4 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[216]
Parameter estimate	Between group GMT ratios
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	1.33

Notes:

[216] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 41
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 6 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[217]
Parameter estimate	Between group GMT ratios
Point estimate	9.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.47
upper limit	17.64

Notes:

[217] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 42

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 6 (Menactra-Menveo vs. Naive)

Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[218]
Parameter estimate	Between group GMT ratios
Point estimate	9.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.31
upper limit	17.19

Notes:

[218] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 43

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 6 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[219]
Parameter estimate	Between group GMT ratios
Point estimate	9.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.59
upper limit	16.79

Notes:

[219] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 44
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 6 (Menveo-Menveo vs. Menactra-Menveo)	
Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[220]
Parameter estimate	Between group GMT ratios
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.54

Notes:

[220] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 45
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 29 (Menveo-Menveo vs. Naive)	
Comparison groups	Menveo-Menveo Group v Naive Group
Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	other[221]
Parameter estimate	Between group GMT ratios
Point estimate	28.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.23
upper limit	40.2

Notes:

[221] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 46
Statistical analysis description:	
Serogroup Y-Vaccine comparison at day 29 (Menactra-Menveo vs. Naive)	
Comparison groups	Naive Group v Menactra-Menveo Group
Number of subjects included in analysis	375
Analysis specification	Pre-specified
Analysis type	other[222]
Parameter estimate	Between group GMT ratios
Point estimate	26.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.09
upper limit	38.02

Notes:

[222] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 47

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 29 (Pooled Menveo-Menveo and Menactra-Menveo vs. Naïve)

Comparison groups	Naive Group v pooled group (menveo-menveo and menactra-menveo)
Number of subjects included in analysis	665
Analysis specification	Pre-specified
Analysis type	other[223]
Parameter estimate	Between group GMT ratios
Point estimate	27.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.1
upper limit	38.26

Notes:

[223] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Statistical analysis title	Statistical analysis 48

Statistical analysis description:

Serogroup Y-Vaccine comparison at day 29 (Menveo-Menveo vs. Menactra-Menveo)

Comparison groups	Menveo-Menveo Group v Menactra-Menveo Group
Number of subjects included in analysis	572
Analysis specification	Pre-specified
Analysis type	other[224]
Parameter estimate	Between group GMT ratios
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.35

Notes:

[224] - GMTs ratio and 95% CI, at each time point against each serogroups A, C, W and Y strains was obtained by exponentiating the mean between-group differences in log-transformed titers and the corresponding 95% CIs at each of the timepoints specified

Secondary: Within group hSBA Geometric Mean Ratios (GMRs)

End point title	Within group hSBA Geometric Mean Ratios (GMRs)

End point description:

Within each study group and for each serogroup, GMRs were calculated,at: Visit Day 4 versus at Visit Day 1; Visit Day 6 versus at Visit Day 1; and Visit Day 29 versus at Visit Day 1. The unadjusted GMRs and 95% CIs are constructed by exponentiating the mean within-group differences in log-transformed titers and the corresponding 95% CIs.

End point type	Secondary

End point timeframe:

At Day 4, Day 6, Day 29 compared to Day 1

End point values	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group	pooled group (menveo-menveo and menactra-menveo)
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	289	282	93	571
Units: Ratios				
geometric mean (confidence interval 95%)				
hSBA-Men A, Day 4/Day 1(N-144,138,48,282)	1.02 (0.93 to 1.12)	1.07 (0.97 to 1.17)	0.99 (0.84 to 1.16)	1.04 (0.98 to 1.11)
hSBA-Men A, Day 6/Day 1(N-145,140,44,285)	4.58 (3.49 to 6)	3.25 (2.46 to 4.28)	1.09 (0.66 to 1.78)	3.87 (3.19 to 4.7)
hSBA-Men A, Day 29/Day 1(N-289,282,93,571)	75.02 (63.87 to 88.12)	80.13 (68.09 to 94.3)	14.14 (10.65 to 18.77)	77.5 (69.12 to 86.9)
hSBA-Men C, Day 4/Day 1(N-143,137,48,280)	1.12 (0.99 to 1.28)	1.35 (1.19 to 1.54)	1.21 (0.97 to 1.51)	1.23 (1.12 to 1.35)
hSBA-Men C, Day 6/Day 1(N-144,139,44,283)	7.25 (5.39 to 9.75)	7.94 (5.87 to 10.73)	1.45 (0.85 to 2.48)	7.58 (6.14 to 9.36)
hSBA-Men C, Day 29/Day 1(N-288,280,93,568)	71.72 (58.88 to 87.37)	97.13 (79.51 to 118.65)	11.81 (8.34 to 16.71)	83.29 (72.34 to 95.89)
hSBA-Men W, Day 4/Day 1(N-144,138,48,282)	1.05 (0.91 to 1.23)	1.4 (1.2 to 1.63)	1.14 (0.88 to 1.48)	1.21 (1.09 to 1.35)
hSBA-Men W, Day 6/Day 1(N-145,140,44,285)	5.71 (4.37 to 7.45)	6.27 (4.78 to 8.23)	1.32 (0.81 to 2.15)	5.98 (4.95 to 7.23)
hSBA-Men W, Day 29/Day 1(N-289,281,92,570)	63.63 (51.37 to 78.81)	80.61 (64.88 to 100.14)	4.57 (3.13 to 6.68)	71.5 (61.38 to 83.27)
hSBA-Men Y, Day 4/Day 1(N-142,137,48,279)	1.35 (1.15 to 1.59)	1.31 (1.11 to 1.54)	0.99 (0.75 to 1.31)	1.33 (1.19 to 1.49)
hSBA-Men Y, Day 6/Day 1(N-143,140,44,283)	6.09 (4.53 to 8.19)	8.59 (6.37 to 11.59)	1.48 (0.87 to 2.52)	7.22 (5.85 to 8.92)
hSBA-Men Y, Day 29/Day 1(N-287,280,93,567)	116.58 (94.42 to 143.95)	123.41 (99.69 to 152.78)	8.21 (5.67 to 11.89)	119.91 (103.21 to 139.3)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were assessed between 6 hours through Day 7. Unsolicited AEs were assessed between Day 1 trough Day 29. SAEs were assessed during the entire study period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Menveo-Menveo Group

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menveo (MenACWY-CRM) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

Reporting group title	Menactra-Menveo Group

Reporting group description:

Healthy subjects, 15 through 55 years of age were vaccinated with a single dose of Menactra (meningococcal diphtheria toxoid-conjugated MenACWY vaccine, MenACWY-D) 4 to 6 years before and received one dose of MenACWY-CRM at Day 1.

Reporting group title	Naive Group

Reporting group description:

Healthy subjects,15 through 55 years of age, who have not received any meningococcal vaccination, received one dose of MenACWY-CRM at Day 1.

Serious adverse events	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 301 (1.00%)	2 / 300 (0.67%)	3 / 100 (3.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Intentional overdose			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Diabetic ketoacidotic hyperglycaemic coma			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			

Abortion spontaneous			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Respiratory disorder			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			

subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Menveo-Menveo Group	Menactra-Menveo Group	Naive Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	243 / 301 (80.73%)	211 / 300 (70.33%)	60 / 100 (60.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign bone neoplasm			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Skin papilloma			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Lymphangiopathy			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Essential hypertension			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	119 / 301 (39.53%)	106 / 300 (35.33%)	41 / 100 (41.00%)
occurrences (all)	124	113	41
Fatigue			

subjects affected / exposed	116 / 301 (38.54%)	111 / 300 (37.00%)	19 / 100 (19.00%)
occurrences (all)	146	159	21
Chills			
subjects affected / exposed	34 / 301 (11.30%)	37 / 300 (12.33%)	10 / 100 (10.00%)
occurrences (all)	36	50	10
Injection site induration			
subjects affected / exposed	17 / 301 (5.65%)	10 / 300 (3.33%)	8 / 100 (8.00%)
occurrences (all)	17	11	9
Injection site erythema			
subjects affected / exposed	14 / 301 (4.65%)	10 / 300 (3.33%)	11 / 100 (11.00%)
occurrences (all)	16	10	14
Pyrexia			
subjects affected / exposed	3 / 301 (1.00%)	7 / 300 (2.33%)	1 / 100 (1.00%)
occurrences (all)	4	8	1
Injection site pruritus			
subjects affected / exposed	1 / 301 (0.33%)	2 / 300 (0.67%)	3 / 100 (3.00%)
occurrences (all)	1	2	3
Influenza like illness			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Chest pain			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Medical device site erythema			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Medical device site swelling			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			

subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vaccination site pruritus			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Axillary pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Hypersensitivity			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Anaphylactic reaction			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Allergy to animal			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Menstruation irregular			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 301 (0.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Metrorrhagia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Pelvic congestion			

subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	7 / 301 (2.33%)	5 / 300 (1.67%)	1 / 100 (1.00%)
occurrences (all)	7	5	1
Asthma			
subjects affected / exposed	7 / 301 (2.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	7	1	0
Nasal congestion			
subjects affected / exposed	2 / 301 (0.66%)	6 / 300 (2.00%)	1 / 100 (1.00%)
occurrences (all)	2	6	1
Cough			
subjects affected / exposed	2 / 301 (0.66%)	6 / 300 (2.00%)	0 / 100 (0.00%)
occurrences (all)	2	6	0
Epistaxis			
subjects affected / exposed	2 / 301 (0.66%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Wheezing			
subjects affected / exposed	2 / 301 (0.66%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	1 / 301 (0.33%)	2 / 300 (0.67%)	1 / 100 (1.00%)
occurrences (all)	1	2	1
Rhinitis allergic			
subjects affected / exposed	1 / 301 (0.33%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Snoring			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			

subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Pulmonary congestion			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Rhonchi			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 301 (1.66%)	3 / 300 (1.00%)	0 / 100 (0.00%)
occurrences (all)	5	3	0
Depression			
subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	4	1	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	2 / 301 (0.66%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Major depression			
subjects affected / exposed	2 / 301 (0.66%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Insomnia			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Sleep disorder			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Disruptive mood dysregulation disorder			

subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Post-traumatic stress disorder			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	4	1	0
Laceration			
subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	4	1	0
Ligament sprain			
subjects affected / exposed	3 / 301 (1.00%)	3 / 300 (1.00%)	0 / 100 (0.00%)
occurrences (all)	3	3	0
Arthropod bite			
subjects affected / exposed	3 / 301 (1.00%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	3	0	0
Concussion			
subjects affected / exposed	2 / 301 (0.66%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	2	2	0
Procedural pain			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	1 / 100 (1.00%)
occurrences (all)	2	1	1
Limb injury			
subjects affected / exposed	2 / 301 (0.66%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Meniscus injury			
subjects affected / exposed	1 / 301 (0.33%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Joint injury			

subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Arthropod sting			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Ligament rupture			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Post procedural complication			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Hand fracture			
subjects affected / exposed	0 / 301 (0.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Alcohol poisoning			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Conjunctival abrasion			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Facial bones fracture			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Pulmonary contusion			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Foot fracture			

subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	103 / 301 (34.22%)	84 / 300 (28.00%)	23 / 100 (23.00%)
occurrences (all)	135	118	27
Syncope			
subjects affected / exposed	2 / 301 (0.66%)	3 / 300 (1.00%)	0 / 100 (0.00%)
occurrences (all)	2	3	0
Migraine			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Loss of consciousness			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Migraine with aura			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 301 (0.00%)	4 / 300 (1.33%)	0 / 100 (0.00%)
occurrences (all)	0	4	0
Presyncope			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Anaemia			

subjects affected / exposed	0 / 301 (0.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane perforation			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Cerumen impaction			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Middle ear effusion			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Oculogyric crisis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Retinal tear			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Eye disorder			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Erythema of eyelid			

subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	51 / 301 (16.94%)	44 / 300 (14.67%)	15 / 100 (15.00%)
occurrences (all)	65	55	17
Abdominal pain			
subjects affected / exposed	5 / 301 (1.66%)	1 / 300 (0.33%)	1 / 100 (1.00%)
occurrences (all)	5	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 301 (0.66%)	3 / 300 (1.00%)	0 / 100 (0.00%)
occurrences (all)	2	3	0
Diarrhoea			
subjects affected / exposed	2 / 301 (0.66%)	2 / 300 (0.67%)	3 / 100 (3.00%)
occurrences (all)	2	2	3
Vomiting			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Tooth impacted			
subjects affected / exposed	2 / 301 (0.66%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Haemorrhoids			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Abdominal tenderness			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	0 / 301 (0.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0

Anal skin tags			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Salivary gland mucocoele			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Umbilical hernia			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Biliary dyskinesia			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	4	1	0
Acne			
subjects affected / exposed	3 / 301 (1.00%)	5 / 300 (1.67%)	0 / 100 (0.00%)
occurrences (all)	3	5	0
Rash			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	1	0
Urticaria			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Alopecia			

subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Rash macular			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Dysuria			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Polyuria			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	57 / 301 (18.94%)	55 / 300 (18.33%)	15 / 100 (15.00%)
occurrences (all)	63	72	15
Arthralgia			
subjects affected / exposed	46 / 301 (15.28%)	41 / 300 (13.67%)	13 / 100 (13.00%)
occurrences (all)	60	50	13
Pain in extremity			

subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	1 / 100 (1.00%)
occurrences (all)	4	1	2
Back pain			
subjects affected / exposed	2 / 301 (0.66%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	2	0	0
Metatarsalgia			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Myalgia intercostal			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Rheumatoid arthritis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Synovial cyst			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Muscle tightness			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	13 / 301 (4.32%)	5 / 300 (1.67%)	2 / 100 (2.00%)
occurrences (all)	16	5	2

Upper respiratory tract infection			
subjects affected / exposed	12 / 301 (3.99%)	9 / 300 (3.00%)	3 / 100 (3.00%)
occurrences (all)	12	9	3
Acute sinusitis			
subjects affected / exposed	11 / 301 (3.65%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	13	0	1
Otitis media			
subjects affected / exposed	4 / 301 (1.33%)	4 / 300 (1.33%)	0 / 100 (0.00%)
occurrences (all)	4	4	0
Bronchitis			
subjects affected / exposed	4 / 301 (1.33%)	3 / 300 (1.00%)	1 / 100 (1.00%)
occurrences (all)	4	3	1
Pneumonia mycoplasmal			
subjects affected / exposed	4 / 301 (1.33%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	4	1	0
Cellulitis			
subjects affected / exposed	4 / 301 (1.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	4	0	0
Influenza			
subjects affected / exposed	3 / 301 (1.00%)	7 / 300 (2.33%)	3 / 100 (3.00%)
occurrences (all)	3	7	3
Pharyngitis			
subjects affected / exposed	3 / 301 (1.00%)	5 / 300 (1.67%)	1 / 100 (1.00%)
occurrences (all)	3	5	1
Pharyngitis streptococcal			
subjects affected / exposed	3 / 301 (1.00%)	3 / 300 (1.00%)	0 / 100 (0.00%)
occurrences (all)	3	3	0
Viral pharyngitis			
subjects affected / exposed	3 / 301 (1.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	4	2	0
Otitis media acute			
subjects affected / exposed	3 / 301 (1.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	3	1	0
Sinusitis			
subjects affected / exposed	2 / 301 (0.66%)	6 / 300 (2.00%)	1 / 100 (1.00%)
occurrences (all)	2	7	1

Urinary tract infection			
subjects affected / exposed	2 / 301 (0.66%)	3 / 300 (1.00%)	2 / 100 (2.00%)
occurrences (all)	2	3	4
Conjunctivitis			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Otitis externa			
subjects affected / exposed	2 / 301 (0.66%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis viral			
subjects affected / exposed	1 / 301 (0.33%)	6 / 300 (2.00%)	0 / 100 (0.00%)
occurrences (all)	1	6	0
Pneumonia			
subjects affected / exposed	1 / 301 (0.33%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	1	2	0
Tooth abscess			
subjects affected / exposed	1 / 301 (0.33%)	1 / 300 (0.33%)	1 / 100 (1.00%)
occurrences (all)	1	1	1
Folliculitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	1	0	1
Bronchitis viral			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Croup infectious			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0

Pneumonia bacterial			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 301 (0.00%)	2 / 300 (0.67%)	0 / 100 (0.00%)
occurrences (all)	0	3	0
Bacterial vaginosis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	1 / 100 (1.00%)
occurrences (all)	0	1	1
Bartholin's abscess			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Chlamydial infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Infectious mononucleosis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0

Rhinitis			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Kidney infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 301 (0.00%)	0 / 300 (0.00%)	1 / 100 (1.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	37 / 301 (12.29%)	48 / 300 (16.00%)	6 / 100 (6.00%)
occurrences (all)	50	63	6
Hypoglycaemia			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 301 (0.33%)	0 / 300 (0.00%)	0 / 100 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 301 (0.00%)	1 / 300 (0.33%)	0 / 100 (0.00%)
occurrences (all)	0	1	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported