Clinical trial results:
Phase 2, Observer-Blind, Placebo-Controlled, Randomized, Multi-Center Extension Study to Evaluate the Safety and Immunogenicity of a Booster Dose of a MenABCWY Vaccine Administered 24 Months Following the Primary Series to Adolescents and Young Adults Who Participated in V102_03.

Summary

EudraCT number	2012-003937-41
Trial protocol	PL
Global end of trial date	17 April 2015
Results information	
Result version number	v1
This version publication date	30 April 2016
First version publication date	30 April 2016

Trial information

Trial identification	
Sponsor protocol code	V102_03E1
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01992536
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Novartis Vaccines & Diagnostic
Sponsor organisation address	Via Fiorentina 1, Siena, Italy, 53100
Public contact	Arkadiusz Stojek, Novartis Vaccines and Diagnostics S.r.l., +48 223754793, arkadiusz.stojek@novartis.com
Scientific contact	Arkadiusz Stojek, Novartis Vaccines and Diagnostics S.r.l., +48 223754793, arkadiusz.stojek@novartis.com

Notes:

Paediatric regulatory details	
Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001260-PIP01-11
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	17 April 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 May 2014
Global end of trial reached?	Yes
Global end of trial date	17 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

1. To evaluate the immune response against meningococcal serogroups A, C, W and Y as measured by percentage of subjects having seroresponse at Day 30 following administration of a booster dose of MenABCWY in subjects who previously received the same vaccine formulation in study V102_03.

2. To evaluate the immune response against strains of serogroup B as measured by percentage of subjects having human serum bactericidal activity (hSBA) titers ≥ 1:5 at Day 30 following administration of a booster dose of MenABCWY in subjects who previously received the same vaccine formulation in study V102_03.
Seroresponse to N. meningitidis serogroups A, C, W and Y is defined as:
▫ For subjects with a pre-vaccination hSBA titer < 1:4, a post-vaccination hSBA titer ≥ 1:8.
▫ For subjects with a pre-vaccination hSBA titer ≥ 1:4, an increase in hSBA titer of at least four times the pre-vaccination titer.

Protection of trial subjects:

This clinical study was designed and shall be implemented and reported in accordance with the International Conference on Harmonisation of Technical requirements (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations including European Directive 2001/20/EC and US Code of Federal Regulations (CFR) Title 21 and with the ethical principles laid down in the Declaration of Helsinki (European Council 2001, US CFR, ICH 1997).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2013
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: 117
Country: Number of subjects enrolled	Poland: 77
Worldwide total number of subjects	194
EEA total number of subjects	77

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)	95
Adults (18-64 years)	99
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 5 study sites in Poland and from 8 study sites in US.

Pre-assignment

Screening details:

All enrolled subjects were included in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Blinding implementation details:

Observer blind

Arms

Are arms mutually exclusive?	Yes
Arm title	2OMV_OMV

Arm description:

Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2OMV_Pbo

Arm description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2qOMV_qOMV

Arm description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

Arm type	Experimental

Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + ¼ OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2qOMV_Pbo

Arm description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2B_OMV

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2B_qOMV

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + ¼ OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	1M_OMV

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	1M_qOMV

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (MenACWY lyophilized) + (rMenB + ¼ OMV NZ) liquid suspension
Investigational medicinal product code	MenACWY + rMenB + ¼ OMV NZ
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	1M_Pbo

Arm description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Arm title	2B_Pbo

Arm description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study.

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL

Number of subjects in period 1[1]	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV
Started	26	25	17
Completed	22	22	16
Not completed	4	3	1
Consent withdrawn by subject	-	1	-
Lost to follow-up	4	2	1
Administrative reason	-	-	-

Number of subjects in period 1[1]	2qOMV_Pbo	2B_OMV	2B_qOMV
Started	24	11	21
Completed	22	11	20
Not completed	2	0	1
Consent withdrawn by subject	2	-	-
Lost to follow-up	-	-	1
Administrative reason	-	-	-

Number of subjects in period 1[1]	1M_OMV	1M_qOMV	1M_Pbo
Started	21	19	19
Completed	21	18	18
Not completed	0	1	1
Consent withdrawn by subject	-	-	-
Lost to follow-up	-	1	1
Administrative reason	-	-	-

Number of subjects in period 1[1]	2B_Pbo
Started	7
Completed	0
Not completed	7
Consent withdrawn by subject	-
Lost to follow-up	-
Administrative reason	7

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: Four subjects in the 194 enrolled were not assigned to any treatment and therefore were not included in any group.

Baseline characteristics

Reporting groups	
Reporting group title	2OMV_OMV
Reporting group description:	
Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study.	
Reporting group title	2OMV_Pbo
Reporting group description:	
Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.	
Reporting group title	2qOMV_qOMV
Reporting group description:	
Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.	
Reporting group title	2qOMV_Pbo
Reporting group description:	
Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.	
Reporting group title	2B_OMV
Reporting group description:	
Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.	
Reporting group title	2B_qOMV
Reporting group description:	
Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.	
Reporting group title	1M_OMV
Reporting group description:	
Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.	
Reporting group title	1M_qOMV
Reporting group description:	
Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.	
Reporting group title	1M_Pbo
Reporting group description:	
Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.	
Reporting group title	2B_Pbo
Reporting group description:	
Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study.	

Reporting group values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV
Number of subjects	26	25	17

Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	18.8	17.1	18
standard deviation	± 5.19	± 4.31	± 5.05
Gender categorical Units: Subjects			
Female	8	13	9
Male	18	12	8

Reporting group values	2qOMV_Pbo	2B_OMV	2B_qOMV
Number of subjects	24	11	21
Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	19	20.9	19.7
standard deviation	± 5.4	± 3.99	± 5.36
Gender categorical Units: Subjects			
Female	14	2	15
Male	10	9	6

Reporting group values	1M_OMV	1M_qOMV	1M_Pbo
Number of subjects	21	19	19
Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	16.8	19.2	17.6
standard deviation	± 4.65	± 6.1	± 5.19
Gender categorical Units: Subjects			
Female	12	12	11
Male	9	7	8

Reporting group values	2B_Pbo	Total	
Number of subjects	7	190	
Age categorical Units: Subjects			

Age continuous Units: months			
arithmetic mean	17.9		
standard deviation	± 4.67	-	

Gender categorical Units: Subjects			
Female	3	99	
Male	4	91	

End points

End points reporting groups

Reporting group title	2OMV_OMV

Reporting group description:

Subjects who previously received two doses of MenABCWY + outer membrane vesicle (OMV) in the parent study, received one booster dose of same vaccine in this study.

Reporting group title	2OMV_Pbo

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

Reporting group title	2qOMV_qOMV

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

Reporting group title	2qOMV_Pbo

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

Reporting group title	2B_OMV

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

Reporting group title	2B_qOMV

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Reporting group title	1M_OMV

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

Reporting group title	1M_qOMV

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Reporting group title	1M_Pbo

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

Reporting group title	2B_Pbo

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of Placebo in this study.

Subject analysis set title	All Enrolled
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All screened subjects who have been enrolled (i.e., attended the first clinic visit and received a subject ID).

Subject analysis set title	Exposed

Subject analysis set type	Intention-to-treat

Subject analysis set description:

All subjects in the Enrolled Population, who received a study vaccination.

Subject analysis set title	Full Analysis Set (FAS) Day 1 (Persistence)
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects in the enrolled population who provided an evaluable serum sample at Visit Day 1.

Subject analysis set title	Full Analysis Set (FAS) Day 30 (Booster)
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects in the enrolled population who were randomised, received the study vaccination in the current study and provided an evaluable serum sample at Visit Day 30 (for Seroresponse, Day 1 and Day 30 samples).

Subject analysis set title	Full Analysis Set (FAS) Day 365 (Persistence of Booster)
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects in the enrolled population who were randomised, received the study vaccination in the current study and provided an evaluable serum sample at Visit Day 365.

Subject analysis set title	Safety set (Solicited AEs)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the Exposed Set with any solicited adverse event (AE) data.

Subject analysis set title	Safety set (Unsolicited AEs)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the Exposed Set with unsolicited AE data.

Subject analysis set title	Safety set (overall)
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects in the exposed population who have either post-vaccination adverse event or safety records.

Subject analysis set title	ABCWY+OMV
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received two doses of MenABCWY+OMV administered two months apart in parent study.

Subject analysis set title	ABCWY+qOMV
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received two doses of MenABCWY+qOMV administered two months apart in parent study.

Subject analysis set title	rMenB+OMV
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received two doses of rMenB + OMV, administered two months apart in parent study.

Subject analysis set title	Menveo
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received one dose of placebo followed by one dose of MenACWY administered two months apart in parent study.

Primary: 1. Percentages of subjects with HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y.

End point title	1. Percentages of subjects with HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y.[1][2]

End point description:

Percentages of subjects having HT-hSBA seroresponse against N. meningitidis serogroups A, C, W and Y, following administration of a booster dose of MenABCWY in the present study, in subjects who previously received the same MenABCWY vaccine formulation in study V102_03.
Seroresponse to N. meningitidis serogroups A, C, W and Y is defined as: for subjects with a pre-vaccination hSBA titer < 1:4, a post-vaccination hSBA titer ≥ 1:8; for subjects with a pre-vaccination hSBA titer ≥ 1:4, an increase in hSBA titer of at least four times the pre-vaccination titer.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, day 1 and day 30 samples were required).

End point type	Primary

End point timeframe:

Day 30

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	16		
Units: Percentage				
number (confidence interval 95%)				
Men A	96 (79.6 to 99.9)	94 (69.8 to 99.84)		
Men C	85 (62.1 to 96.8)	100 (69.2 to 100)		
Men W	85 (62.1 to 96.8)	85 (54.6 to 98.1)		
Men Y	96 (79.6 to 99.9)	100 (76.8 to 100)		

Statistical analyses

No statistical analyses for this end point

Primary: 2. Percentage of subjects with HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B.

End point title	2. Percentage of subjects with HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B.[3][4]

End point description:

Percentage of subjects reporting HT-hSBA titers ≥ 1:5 against strains of N. meningitidis serogroup B at Day 1 (24 months after the last vaccination in the primary series of study V102_03) and one month (Day 30) following administration of a booster dose of MenABCWY in the present study, in subjects who previously received the same MenABCWY vaccine formulation in study V102_03.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Primary

End point timeframe:

Day 1 and Day 30

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	17		
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	24 (9.4 to 45.1)	7 (0.17 to 31.9)		
M14459 (fHBP) (Day 30)	92 (74 to 99)	88 (63.6 to 98.5)		
M01-0240364 (NadA) (Day 1)	25 (9.8 to 46.7)	20 (4.3 to 48.1)		
M01-0240364 (NadA) (Day 30)	100 (86.3 to 100)	100 (80.5 to 100)		
NZ98/254 (PorA) (Day 1)	16 (4.5 to 36.1)	7 (0.17 to 31.9)		
NZ98/254 (PorA) (Day 30)	92 (74 to 99)	71 (44 to 89.7)		
M07-0241084 (NHBA) (Day 1)	36 (18 to 57.5)	27 (7.8 to 55.1)		
M07-0241084 (NHBA) (Day 30)	100 (86.3 to 100)	88 (63.6 to 98.5)		
H44/76 (fHBP) (Day 1)	16 (4.5 to 36.1)	13 (1.6 to 38.3)		
H44/76 (fHBP) (Day 30)	96 (79.6 to 99.9)	100 (80.5 to 100)		
5/99 (NadA) (Day 1)	76 (54.9 to 90.6)	87 (59.5 to 98.3)		
5/99 (NadA) (Day 30)	100 (86.3 to 100)	100 (80.5 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: 3. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.

End point title	3. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:8 in serogroups A, C, W, Y against N. meningitidis assessed prior to the administration of MenABCWY booster vaccination or placebo.
Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.
Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

End point type	Secondary

End point timeframe:

Day 1 (Pre vaccination)

End point values	ABCWY+OMV	ABCWY+qOMV	rMenB+OMV	Menveo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	40	38	59
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	27 (15.9 to 41.7)	28 (14.6 to 43.9)	29 (15.4 to 45.9)	31 (19.5 to 44.5)
Men C (Day 1)	67 (51.6 to 79.6)	68 (51.3 to 82.5)	45 (28.6 to 61.7)	57 (43.2 to 69.8)
Men W (Day 1)	92 (80.8 to 97.8)	75 (57.8 to 87.9)	76 (59.8 to 88.6)	68 (54 to 79.7)
Men Y (Day 1)	65 (50.1 to 77.6)	50 (33.4 to 66.6)	16 (6 to 31.3)	46 (32.7 to 59.2)

Statistical analyses

No statistical analyses for this end point

Secondary: 4. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis strains of serogroup B.

End point title	4. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis strains of serogroup B.

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:5 against N. meningitidis strains of serogroup B assessed prior to the administration of MenABCWY booster vaccination or placebo.
Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.
Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

End point type	Secondary

End point timeframe:

Day 1 (Pre vaccination)

End point values	ABCWY+OMV	ABCWY+qOMV	rMenB+OMV	Menveo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	39	38	59
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	29 (17.5 to 43.8)	13 (4.3 to 27.4)	26 (13.4 to 43.1)	14 (6 to 25)
M01-0240364 (NadA) (Day 1)	24 (13.1 to 38.2)	16 (6.2 to 32)	35 (20.2 to 52.5)	7 (1.9 to 16.7)
NZ98/254 (PorA) (Day 1)	24 (12.8 to 37.5)	8 (1.6 to 20.9)	16 (6 to 31.3)	3 (0.41 to 11.7)
M07-0241084 (NHBA) (Day 1)	37 (24.1 to 51.9)	29 (15.4 to 45.9)	50 (33.4 to 66.6)	22 (12.3 to 34.7)

H44/76 (fHBP) (Day 1)	22 (11.3 to 35.3)	18 (7.5 to 33.5)	34 (19.6 to 51.4)	3 (0.41 to 11.7)
5/99 (NadA) (Day 1)	76 (62.5 to 87.2)	87 (71.9 to 95.6)	94 (81.3 to 99.3)	19 (9.7 to 30.9)

Statistical analyses

No statistical analyses for this end point

Secondary: 5. The HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroups A, C, W, Y.

End point title	5. The HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroups A, C, W, Y.

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y prior to the administration of MenABCWY booster vaccination or placebo.
Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.
Analysis was done on FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

End point type	Secondary

End point timeframe:

Day 1 (Pre vaccination)

End point values	ABCWY+OMV	ABCWY+qOMV	rMenB+OMV	Menveo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	40	38	59
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	3.34 (2.19 to 5.08)	3.3 (1.95 to 5.6)	2.96 (1.7 to 5.17)	4.14 (2.75 to 6.23)
Men C (Day 1)	18 (11 to 30)	13 (8 to 20)	6.05 (4.28 to 8.55)	10 (6.36 to 17)
Men W (Day 1)	35 (24 to 52)	23 (12 to 45)	20 (11 to 34)	17 (9.65 to 29)
Men Y (Day 1)	13 (7.01 to 23)	8.85 (4.24 to 18)	1.8 (1.25 to 2.6)	6.49 (3.72 to 11)

Statistical analyses

No statistical analyses for this end point

Secondary: 6. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

End point title	6. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B prior the administration of MenABCWY booster vaccination or placebo.

Pre vaccination is 24 months after completion of the primary vaccination series, in subjects who previously received the same vaccine formulation in study V102_03.
Analysis was done on the FAS Day 1 (Persistence) population. All subjects in the enrolled population who provided an evaluable serum sample at Day 1.

End point type	Secondary

End point timeframe:

Day 1 (Pre vaccination)

End point values	ABCWY+OMV	ABCWY+qOMV	rMenB+OMV	Menveo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	39	38	59
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP)	2.67 (1.92 to 3.7)	1.94 (1.48 to 2.56)	2.82 (2 to 3.96)	1.87 (1.43 to 2.43)
M01-0240364 (NadA)	2.67 (1.7 to 4.2)	2.1 (1.21 to 3.65)	4.72 (2.44 to 9.13)	1.37 (1.06 to 1.78)
NZ98/254 (PorA)	2.03 (1.43 to 2.89)	1.46 (1.15 to 1.85)	1.75 (1.24 to 2.47)	1.16 (1 to 1.34)
M07-0241084 (NHBA)	3.76 (2.55 to 5.56)	2.42 (1.7 to 3.45)	4.56 (2.97 to 7.01)	2.35 (1.68 to 3.28)
H44/76 (fHBP)	2.54 (1.69 to 3.82)	1.78 (1.26 to 2.53)	3.22 (2.18 to 4.76)	1.32 (1.06 to 1.65)
5/99 (NadA)	16 (11 to 24)	33 (19 to 54)	39 (25 to 62)	2.46 (1.73 to 3.51)

Statistical analyses

No statistical analyses for this end point

Secondary: 7. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

End point title	7. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.[5]

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at Day 1 and one month after the administration of MenABCWY booster vaccination or placebo.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 1 and Day 30

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	16	23
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	3.41 (1.87 to 6.22)	2.92 (1.59 to 5.36)	2.86 (1.23 to 6.63)	2.73 (1.41 to 5.27)
Men A (Day 30)	259 (174 to 383)	4.28 (2.03 to 9.03)	333 (199 to 559)	3.07 (1.51 to 6.25)
Men C (Day 1)	23 (9.45 to 57)	16 (7.06 to 36)	17 (5.98 to 51)	11 (6.24 to 19)
Men C (Day 30)	660 (401 to 1084)	17 (7.6 to 38)	612 (245 to 1524)	11 (5.51 to 22)
Men W (Day 1)	34 (20 to 59)	33 (17 to 65)	30 (8.9 to 101)	18 (7.3 to 46)
Men W (Day 30)	792 (516 to 1216)	34 (16 to 71)	880 (671 to 1154)	26 (11 to 59)
Men Y (Day 1)	10 (4.89 to 21)	15 (5.5 to 43)	15 (4.33 to 53)	5.66 (2.25 to 14)
Men Y (Day 30)	464 (294 to 734)	16 (5.65 to 48)	697 (435 to 1116)	5.17 (2.16 to 12)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	18
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	2.26 (0.96 to 5.31)	3.94 (1.58 to 9.85)	6.62 (2.85 to 15)	2.09 (1.28 to 3.41)
Men A (Day 30)	438 (287 to 670)	416 (198 to 871)	138 (84 to 229)	46 (24 to 87)
Men C (Day 1)	5.45 (2.41 to 12)	9.02 (5.24 to 16)	7.75 (4.19 to 14)	7.53 (2.38 to 24)
Men C (Day 30)	292 (75 to 1142)	135 (69 to 261)	338 (205 to 558)	304 (124 to 742)
Men W (Day 1)	25 (7.98 to 79)	29 (13 to 64)	28 (12 to 66)	9.37 (2.85 to 31)
Men W (Day 30)	392 (252 to 610)	363 (278 to 473)	629 (384 to 1032)	364 (180 to 736)
Men Y (Day 1)	2.4 (1.05 to 5.47)	1.84 (1.07 to 3.14)	6.43 (2.86 to 14)	5.79 (1.77 to 19)
Men Y (Day 30)	48 (14 to 157)	39 (13 to 120)	658 (431 to 1003)	419 (217 to 809)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Titers				
geometric mean (confidence interval 95%)				

Men A (Day 1)	5.02 (2.06 to 12)			
Men A (Day 30)	4.91 (2 to 12)			
Men C (Day 1)	17 (6.6 to 44)			
Men C (Day 30)	20 (7.2 to 56)			
Men W (Day 1)	9.42 (3.03 to 29)			
Men W (Day 30)	16 (4.87 to 53)			
Men Y (Day 1)	5.32 (1.81 to 16)			
Men Y (Day 30)	6.36 (1.91 to 21)			

Statistical analyses

No statistical analyses for this end point

Secondary: 8. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

End point title	8. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.[6]

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B at Day 1 and one month after the administration of MenABCWY booster vaccination or placebo.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 1 and Day 30

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	17	23
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	2.57 (1.57 to 4.22)	2.58 (1.62 to 4.12)	1.6 (0.97 to 2.65)	2.27 (1.61 to 3.2)
M14459 (fHBP) (Day 30)	31 (18 to 54)	2.18 (1.39 to 3.42)	20 (11 to 37)	2.33 (1.62 to 3.35)
M01-0240364 (NadA) (Day 1)	2.28 (1.3 to 3.98)	3.11 (1.44 to 6.68)	2.67 (0.87 to 8.24)	1.36 (0.83 to 2.23)
M01-0240364 (NadA) (Day 30)	685 (397 to 1182)	3.21 (1.4 to 7.37)	856 (454 to 1614)	1.94 (1.02 to 3.69)
NZ98/254 (PorA) (Day 1)	1.65 (1.09 to 2.48)	2.11 (1.28 to 3.49)	1.32 (0.94 to 1.84)	1.58 (1.11 to 2.27)
NZ98/254 (PorA) (Day 30)	29 (18 to 47)	2.03 (1.21 to 3.4)	12 (5.04 to 31)	1.87 (1.11 to 3.16)
M07-0241084 (NHBA) (Day 1)	3.53 (2.09 to 5.95)	3.54 (1.98 to 6.31)	2.16 (1.15 to 4.08)	2.52 (1.58 to 4.03)

M07-0241084 (NHBA) (Day 30)	50 (31 to 79)	3.66 (2.02 to 6.64)	29 (14 to 58)	2.48 (1.55 to 3.96)
H44/76 (fHBP) (Day 1)	2.92 (1.5 to 5.67)	2.03 (1.23 to 3.34)	1.46 (0.96 to 2.21)	1.92 (1.11 to 3.32)
H44/76 (fHBP) (Day 30)	97 (60 to 157)	2.36 (1.39 to 4.01)	56 (32 to 97)	2.54 (1.42 to 4.53)
5/99 (NadA) (Day 1)	17 (9.56 to 29)	16 (8.32 to 30)	35 (14 to 92)	30 (15 to 60)
5/99 (NadA) (Day 30)	1131 (716 to 1787)	20 (10 to 42)	1598 (900 to 2840)	34 (20 to 59)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	3.11 (1.74 to 5.56)	3.18 (1.87 to 5.41)	1.91 (1.14 to 3.2)	1.45 (1.03 to 2.05)
M14459 (fHBP) (Day 30)	56 (27 to 117)	35 (21 to 58)	3.44 (2.05 to 5.75)	2.57 (1.51 to 4.37)
M01-0240364 (NadA) (Day 1)	2.46 (0.72 to 8.4)	6.81 (2.47 to 19)	1.34 (0.84 to 2.13)	1.23 (0.88 to 1.71)
M01-0240364 (NadA) (Day 30)	1336 (810 to 2202)	1275 (794 to 2048)	3.5 (1.32 to 9.3)	3.42 (1.19 to 9.8)
NZ98/254 (PorA) (Day 1)	1.72 (0.99 to 2.98)	2.07 (1.17 to 3.66)	1.18 (0.84 to 1.66)	1.18 (0.9 to 1.54)
NZ98/254 (PorA) (Day 30)	17 (6.22 to 45)	28 (17 to 44)	2.48 (1.31 to 4.69)	1.58 (0.96 to 2.59)
M07-0241084 (NHBA) (Day 1)	4.1 (1.89 to 8.9)	6.08 (3.18 to 12)	2.08 (1.26 to 3.42)	2.06 (1.13 to 3.77)
M07-0241084 (NHBA) (Day 30)	68 (33 to 142)	69 (36 to 129)	3.26 (1.75 to 6.06)	2.15 (1.13 to 4.07)
H44/76 (fHBP) (Day 1)	3.45 (1.81 to 6.57)	3.24 (1.76 to 5.94)	1.09 (0.96 to 1.22)	1.47 (0.92 to 2.36)
H44/76 (fHBP) (Day 30)	132 (64 to 271)	79 (42 to 149)	5.27 (2.54 to 11)	3.85 (1.85 to 8.02)
5/99 (NadA) (Day 1)	27 (8.61 to 86)	43 (24 to 77)	2.97 (1.58 to 5.59)	1.74 (1.01 to 3.03)
5/99 (NadA) (Day 30)	2205 (1560 to 3117)	2576 (1716 to 3867)	28 (11 to 67)	30 (11 to 78)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	2.37 (1.31 to 4.29)			
M14459 (fHBP) (Day 30)	2.93 (1.14 to 7.53)			
M01-0240364 (NadA) (Day 1)	1.63 (0.86 to 3.11)			

M01-0240364 (NadA) (Day 30)	1.76 (0.75 to 4.09)			
NZ98/254 (PorA) (Day 1)	1.12 (0.94 to 1.34)			
NZ98/254 (PorA) (Day 30)	1.71 (0.84 to 3.5)			
M07-0241084 (NHBA) (Day 1)	3.01 (1.38 to 6.56)			
M07-0241084 (NHBA) (Day 30)	3.86 (1.4 to 11)			
H44/76 (fHBP) (Day 1)	1.18 (0.97 to 1.44)			
H44/76 (fHBP) (Day 30)	1.63 (0.75 to 3.52)			
5/99 (NadA) (Day 1)	2.81 (1.3 to 6.06)			
5/99 (NadA) (Day 30)	3.41 (1.2 to 9.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.

End point title	9. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.[7]

End point description:

Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains, from baseline to one month after the administration of MenABCWY booster vaccination or placebo.
Four-fold rise is defined as follows: for subjects with a pre-vaccination titer < 1:2, a post-titer of ≥ 1:8; for subjects with a pre-vaccination titer ≥ 1:2 at least a four-fold increase.
Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 30

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	16	23
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP)	72 (50.6 to 87.9)	0 (0 to 13.7)	87 (59.5 to 98.3)	0 (0 to 14.8)
M01-0240364 (NadA)	100 (85.8 to 100)	4 (0.1 to 20.4)	93 (68.1 to 99.83)	5 (0.13 to 24.9)
NZ98/254 (PorA)	76 (54.9 to 90.6)	0 (0 to 13.7)	67 (38.4 to 88.2)	4 (0.11 to 21.9)
M07-0241084 (NHBA)	76 (54.9 to 90.6)	0 (0 to 13.7)	87 (59.5 to 98.3)	0 (0 to 15.4)

H44/76 (fHBP)	84 (63.9 to 95.5)	4 (0.1 to 20.4)	94 (69.8 to 99.84)	0 (0 to 15.4)
5/99 (NadA)	100 (86.3 to 100)	4 (0.1 to 20.4)	93 (68.1 to 99.83)	0 (0 to 15.4)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP)	100 (71.5 to 100)	76 (52.8 to 91.8)	15 (3.2 to 37.9)	5 (0.13 to 26)
M01-0240364 (NadA)	100 (69.2 to 100)	90 (69.6 to 98.8)	20 (5.7 to 43.7)	22 (6.4 to 47.6)
NZ98/254 (PorA)	82 (48.2 to 97.7)	67 (43 to 85.4)	19 (5.4 to 41.9)	5 (0.13 to 26)
M07-0241084 (NHBA)	82 (48.2 to 97.7)	62 (38.4 to 81.9)	14 (3 to 36.3)	0 (0 to 17.6)
H44/76 (fHBP)	100 (71.5 to 100)	76 (52.8 to 91.8)	37 (16.3 to 61.6)	26 (9.1 to 51.2)
5/99 (NadA)	100 (66.4 to 100)	95 (76.2 to 99.88)	57 (34 to 78.2)	79 (54.4 to 93.9)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP)	6 (0.14 to 27.3)			
M01-0240364 (NadA)	6 (0.14 to 27.3)			
NZ98/254 (PorA)	6 (0.14 to 27.3)			
M07-0241084 (NHBA)	6 (0.14 to 27.3)			
H44/76 (fHBP)	6 (0.14 to 27.3)			
5/99 (NadA)	6 (0.14 to 27.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: 10. Percentage of subjects with HT-hSBA titer ≥ 1:8 against N. meningitidis serogroups A ,C, W, Y.

End point title	10. Percentage of subjects with HT-hSBA titer ≥ 1:8 against N.

	meningitidis serogroups A ,C, W, Y.[8]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y at Day 1 and 30 Days after the administration of a booster dose of MenABCWY vaccine or placebo in this study. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 1 and Day 30

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	16	23
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	32 (14.9 to 53.5)	20 (6.8 to 40.7)	19 (4 to 45.6)	27 (10.7 to 50.2)
Men A (Day 30)	100 (86.3 to 100)	36 (18 to 57.5)	100 (79.4 to 100)	27 (10.7 to 50.2)
Men C (Day 1)	70 (45.7 to 88.1)	65 (42.7 to 83.6)	70 (34.8 to 93.3)	68 (45.1 to 86.1)
Men C (Day 30)	100 (83.9 to 100)	63 (40.6 to 81.2)	100 (71.5 to 100)	61 (38.5 to 80.3)
Men W (Day 1)	95 (75.1 to 99.87)	88 (67.6 to 97.3)	77 (46.2 to 95)	71 (47.8 to 88.7)
Men W (Day 30)	100 (83.2 to 100)	79 (57.8 to 92.9)	100 (79.4 to 100)	77 (54.6 to 92.2)
Men Y (Day 1)	64 (42.5 to 82)	64 (42.5 to 82)	64 (35.1 to 87.2)	41 (20.7 to 63.6)
Men Y (Day 30)	100 (86.3 to 100)	60 (38.7 to 78.9)	100 (79.4 to 100)	39 (19.7 to 61.5)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	18
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	27 (6 to 61)	33 (14.6 to 57)	47 (24.4 to 71.1)	6 (0.16 to 30.2)
Men A (Day 30)	100 (71.5 to 100)	95 (76.2 to 99.88)	100 (82.4 to 100)	94 (71.3 to 99.85)
Men C (Day 1)	43 (9.9 to 81.6)	63 (35.4 to 84.8)	57 (34 to 78.2)	44 (21.5 to 69.2)
Men C (Day 30)	100 (59 to 100)	100 (79.4 to 100)	100 (83.9 to 100)	89 (65.3 to 98.6)
Men W (Day 1)	82 (48.2 to 97.7)	79 (54.4 to 93.9)	83 (58.6 to 96.4)	53 (27.8 to 77)
Men W (Day 30)	100 (71.5 to 100)	100 (82.4 to 100)	100 (82.4 to 100)	100 (80.5 to 100)

Men Y (Day 1)	36 (10.9 to 69.2)	10 (1.2 to 30.4)	52 (29.8 to 74.3)	39 (17.3 to 64.3)
Men Y (Day 30)	82 (48.2 to 97.7)	76 (52.8 to 91.8)	100 (83.9 to 100)	100 (81.5 to 100)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	39 (17.3 to 64.3)			
Men A (Day 30)	39 (17.3 to 64.3)			
Men C (Day 1)	65 (38.3 to 85.8)			
Men C (Day 30)	61 (35.7 to 82.7)			
Men W (Day 1)	53 (26.6 to 78.7)			
Men W (Day 30)	63 (35.4 to 84.8)			
Men Y (Day 1)	39 (17.3 to 64.3)			
Men Y (Day 30)	39 (17.3 to 64.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Percentage of subjects with HT-hSBA titer ≥ 1:5 against N. meningitidis serogroup B strains.

End point title	11. Percentage of subjects with HT-hSBA titer ≥ 1:5 against N. meningitidis serogroup B strains.[9]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis serogroup B strains at Day 1 and 30 Days after the administration of a booster dose of MenABCWY vaccine or placebo in this study. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 1 and Day 30

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	17	23
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	24 (9.4 to 45.1)	32 (14.9 to 53.5)	7 (0.17 to 31.9)	17 (5 to 38.8)
M14459 (fHBP) (Day 30)	92 (74 to 99)	28 (12.1 to 49.4)	88 (63.6 to 98.5)	30 (13.2 to 52.9)
M01-0240364 (NadA) (Day 1)	25 (9.8 to 46.7)	24 (9.4 to 45.1)	20 (4.3 to 48.1)	5 (0.13 to 24.9)
M01-0240364 (NadA) (Day 30)	100 (86.3 to 100)	24 (9.4 to 45.1)	100 (80.5 to 100)	18 (5.2 to 40.3)
NZ98/254 (PorA) (Day 1)	16 (4.5 to 36.1)	28 (12.1 to 49.4)	7 (0.17 to 31.9)	9 (1.1 to 28)
NZ98/254 (PorA) (Day 30)	92 (74 to 99)	20 (6.8 to 40.7)	71 (44 to 89.7)	13 (2.8 to 33.6)
M07-0241084 (NHBA) (Day 1)	36 (18 to 57.5)	36 (18 to 57.5)	27 (7.8 to 55.1)	27 (10.7 to 50.2)
M07-0241084 (NHBA) (Day 30)	100 (86.3 to 100)	40 (21.1 to 61.3)	88 (63.6 to 98.5)	30 (13.2 to 52.9)
H44/76 (fHBP) (Day 1)	16 (4.5 to 36.1)	24 (9.4 to 45.1)	13 (1.6 to 38.3)	18 (5.2 to 40.3)
H44/76 (fHBP) (Day 30)	96 (79.6 to 99.9)	24 (9.4 to 45.1)	100 (80.5 to 100)	26 (10.2 to 48.4)
5/99 (NadA) (Day 1)	76 (54.9 to 90.6)	76 (54.9 to 90.6)	87 (59.5 to 98.3)	86 (65.1 to 97.1)
5/99 (NadA) (Day 30)	100 (86.3 to 100)	84 (63.9 to 95.5)	100 (80.5 to 100)	91 (72 to 98.9)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	36 (10.9 to 69.2)	29 (11.3 to 52.2)	10 (1.2 to 31.7)	11 (1.3 to 33.1)
M14459 (fHBP) (Day 30)	100 (71.5 to 100)	95 (76.2 to 99.88)	35 (15.4 to 59.2)	32 (12.6 to 56.6)
M01-0240364 (NadA) (Day 1)	20 (2.5 to 55.6)	43 (21.8 to 66)	5 (0.13 to 24.9)	6 (0.14 to 27.3)
M01-0240364 (NadA) (Day 30)	100 (71.5 to 100)	100 (83.9 to 100)	25 (8.7 to 49.1)	26 (9.1 to 51.2)
NZ98/254 (PorA) (Day 1)	9 (0.23 to 41.3)	24 (8.2 to 47.2)	5 (0.12 to 23.8)	5 (0.13 to 26)
NZ98/254 (PorA) (Day 30)	82 (48.2 to 97.7)	95 (76.2 to 99.88)	19 (5.4 to 41.9)	16 (3.4 to 39.6)
M07-0241084 (NHBA) (Day 1)	64 (30.8 to 89.1)	52 (29.8 to 74.3)	19 (5.4 to 41.9)	16 (3.4 to 39.6)
M07-0241084 (NHBA) (Day 30)	91 (58.7 to 99.77)	95 (76.2 to 99.88)	33 (14.6 to 57)	21 (6.1 to 45.6)
H44/76 (fHBP) (Day 1)	45 (16.7 to 76.6)	29 (11.3 to 52.2)	0 (0 to 17.6)	5 (0.13 to 26)
H44/76 (fHBP) (Day 30)	100 (71.5 to 100)	100 (83.9 to 100)	58 (33.5 to 79.7)	32 (12.6 to 56.6)

5/99 (NadA) (Day 1)	89 (51.8 to 99.72)	95 (76.2 to 99.88)	19 (5.4 to 41.9)	16 (3.4 to 39.6)
5/99 (NadA) (Day 30)	100 (71.5 to 100)	100 (83.9 to 100)	76 (52.8 to 91.8)	84 (60.4 to 96.6)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	22 (6.4 to 47.6)			
M14459 (fHBP) (Day 30)	22 (6.4 to 47.6)			
M01-0240364 (NadA) (Day 1)	11 (1.4 to 34.7)			
M01-0240364 (NadA) (Day 30)	11 (1.4 to 34.7)			
NZ98/254 (PorA) (Day 1)	0 (0 to 18.5)			
NZ98/254 (PorA) (Day 30)	6 (0.14 to 27.3)			
M07-0241084 (NHBA) (Day 1)	33 (13.3 to 59)			
M07-0241084 (NHBA) (Day 30)	33 (13.3 to 59)			
H44/76 (fHBP) (Day 1)	0 (0 to 18.5)			
H44/76 (fHBP) (Day 30)	6 (0.14 to 27.3)			
5/99 (NadA) (Day 1)	22 (6.4 to 47.6)			
5/99 (NadA) (Day 30)	22 (6.4 to 47.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y, at Day 30 after booster vaccination.

End point title	12. Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y, at Day 30 after booster vaccination.[10]

End point description:

Percentage of subjects with seroresponse to N. meningitidis serogroups A, C, W and Y at Day 30 after the administration of a booster dose of MenABCWY vaccine or placebo in this study, versus baseline. Analysis was done on FAS Day 30 (Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at day 30 (for seroresponse, Day 1 and Day 30 samples were required).

End point type	Secondary

End point timeframe:

Day 30

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	25	16	23
Units: Percentage				
number (confidence interval 95%)				
Men A overall	96 (79.6 to 99.9)	32 (14.9 to 53.5)	100 (79.4 to 100)	18 (5.2 to 40.3)
Men C overall	95 (76.2 to 99.88)	52 (30.6 to 73.2)	100 (71.5 to 100)	30 (13.2 to 52.9)
Men W overall	95 (75.1 to 99.87)	33 (14.6 to 57)	100 (79.4 to 100)	45 (23.1 to 68.5)
Men Y overall	100 (86.3 to 100)	46 (25.6 to 67.2)	100 (79.4 to 100)	30 (13.2 to 52.9)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	16
Units: Percentage				
number (confidence interval 95%)				
Men A overall	100 (71.5 to 100)	95 (76.2 to 99.88)	100 (82.4 to 100)	93 (68.1 to 99.83)
Men C overall	100 (59 to 100)	81 (54.4 to 96)	100 (83.9 to 100)	88 (61.7 to 98.4)
Men W overall	100 (71.5 to 100)	82 (56.6 to 96.2)	88 (61.7 to 98.4)	92 (64 to 99.81)
Men Y overall	82 (48.2 to 97.7)	71 (47.8 to 88.7)	100 (83.9 to 100)	100 (79.4 to 100)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage				
number (confidence interval 95%)				
Men A overall	29 (10.3 to 56)			
Men C overall	41 (18.4 to 67.1)			
Men W overall	27 (7.8 to 55.1)			
Men Y overall	25 (7.3 to 52.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.

End point title	13. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.[11]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:8 against N. meningitidis serogroups A, C, W, Y at 24 and 36 months after the primary vaccination.
Analysis was done on the FAS Day 365 (Persistence of Booster) population. All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1 and Day 365

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	22	16	20
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	38 (18.1 to 61.6)	18 (5.2 to 40.3)	20 (4.3 to 48.1)	30 (11.9 to 54.3)
Men A (Day 365)	67 (43 to 85.4)	23 (7.8 to 45.4)	88 (61.7 to 98.4)	25 (8.7 to 49.1)
Men C (Day 1)	65 (40.8 to 84.6)	68 (43.4 to 87.4)	71 (41.9 to 91.6)	65 (40.8 to 84.6)
Men C (Day 365)	100 (83.9 to 100)	62 (38.4 to 81.9)	100 (79.4 to 100)	50 (27.2 to 72.8)
Men W (Day 1)	95 (75.1 to 99.87)	95 (77.2 to 99.88)	75 (42.8 to 94.5)	70 (45.7 to 88.1)
Men W (Day 365)	100 (83.9 to 100)	82 (59.7 to 94.8)	100 (79.4 to 100)	65 (40.8 to 84.6)
Men Y (Day 1)	62 (38.4 to 81.9)	62 (38.4 to 81.9)	71 (41.9 to 91.6)	40 (19.1 to 63.9)
Men Y (Day 365)	95 (76.2 to 99.88)	52 (29.8 to 74.3)	100 (79.4 to 100)	40 (19.1 to 63.9)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	20	20	18
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	30 (6.7 to 65.2)	35 (15.4 to 59.2)	45 (23.1 to 68.5)	12 (1.5 to 36.4)
Men A (Day 365)	90 (55.5 to 99.75)	85 (62.1 to 96.8)	85 (62.1 to 96.8)	50 (26 to 74)

Men C (Day 1)	36 (10.9 to 69.2)	58 (33.5 to 79.7)	58 (33.5 to 79.7)	50 (26 to 74)
Men C (Day 365)	82 (48.2 to 97.7)	95 (74 to 99.87)	100 (82.4 to 100)	89 (65.3 to 98.6)
Men W (Day 1)	82 (48.2 to 97.7)	75 (50.9 to 91.3)	82 (56.6 to 96.2)	61 (35.7 to 82.7)
Men W (Day 365)	91 (58.7 to 99.77)	100 (83.2 to 100)	100 (82.4 to 100)	100 (81.5 to 100)
Men Y (Day 1)	36 (10.9 to 69.2)	11 (1.4 to 34.7)	55 (31.5 to 76.9)	44 (21.5 to 69.2)
Men Y (Day 365)	45 (16.7 to 76.6)	72 (46.5 to 90.3)	100 (83.2 to 100)	89 (65.3 to 98.6)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	41 (18.4 to 67.1)			
Men A (Day 365)	35 (14.2 to 61.7)			
Men C (Day 1)	75 (47.6 to 92.7)			
Men C (Day 365)	65 (38.3 to 85.8)			
Men W (Day 1)	56 (29.9 to 80.2)			
Men W (Day 365)	65 (38.3 to 85.8)			
Men Y (Day 1)	41 (18.4 to 67.1)			
Men Y (Day 365)	47 (23 to 72.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis strains of serogroup B.

End point title	14. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis strains of serogroup B.[12]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:5 against N. meningitidis strains of serogroup B at 24 and 36 months after the primary vaccination.
Analysis was done on FAS Day 30 (Booster) and FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 30 and Day 365.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	22	16	20
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	24 (8.2 to 47.2)	36 (17.2 to 59.3)	7 (0.18 to 33.9)	15 (3.2 to 37.9)
M14459 (fHBP) (Day 30)	95 (76.2 to 99.88)	32 (13.9 to 54.9)	88 (61.7 to 98.4)	20 (5.7 to 43.7)
M14459 (fHBP) (Day 365)	57 (34 to 78.2)	18 (5.2 to 40.3)	38 (15.2 to 64.6)	5 (0.13 to 24.9)
M01-0240364 (NadA) (Day 1)	24 (8.2 to 47.2)	27 (10.7 to 50.2)	21 (4.7 to 50.8)	6 (0.14 to 27.3)
M01-0240364 (NadA) (Day 30)	100 (83.9 to 100)	27 (10.7 to 50.2)	100 (79.4 to 100)	6 (0.15 to 28.7)
M01-0240364 (NadA) (Day 365)	71 (47.8 to 88.7)	32 (13.9 to 54.9)	75 (47.6 to 92.7)	6 (0.14 to 27.3)
NZ98/254 (PorA) (Day 1)	19 (5.4 to 41.9)	32 (13.9 to 54.9)	7 (0.18 to 33.9)	5 (0.13 to 24.9)
NZ98/254 (PorA) (Day 30)	95 (76.2 to 99.88)	23 (7.8 to 45.4)	75 (47.6 to 92.7)	10 (1.2 to 31.7)
NZ98/254 (PorA) (Day 365)	29 (11.3 to 52.2)	14 (2.9 to 34.9)	31 (11 to 58.7)	5 (0.13 to 24.9)
M07-0241084 (NHBA) (Day 1)	38 (18.1 to 61.6)	41 (20.7 to 63.6)	29 (8.4 to 58.1)	25 (8.7 to 49.1)
M07-0241084 (NHBA) (Day 30)	100 (83.9 to 100)	45 (24.4 to 67.8)	94 (69.8 to 99.84)	25 (8.7 to 49.1)
M07-0241084 (NHBA) (Day 365)	62 (38.4 to 81.9)	32 (13.9 to 54.9)	50 (24.7 to 75.3)	20 (5.7 to 43.7)
H44/76 (fHBP) (Day 1)	19 (5.4 to 41.9)	27 (10.7 to 50.2)	13 (1.7 to 40.5)	15 (3.2 to 37.9)
H44/76 (fHBP) (Day 30)	95 (76.2 to 99.88)	27 (10.7 to 50.2)	100 (79.4 to 100)	15 (3.2 to 37.9)
H44/76 (fHBP) (Day 365)	76 (52.8 to 91.8)	18 (5.2 to 40.3)	44 (19.8 to 70.1)	10 (1.2 to 31.7)
5/99 (NadA) (Day 1)	76 (52.8 to 91.8)	82 (59.7 to 94.8)	86 (57.2 to 98.2)	85 (62.1 to 96.8)
5/99 (NadA) (Day 30)	100 (83.9 to 100)	86 (65.1 to 97.1)	100 (79.4 to 100)	90 (68.3 to 98.8)
5/99 (NadA) (Day 365)	95 (76.2 to 99.88)	77 (54.6 to 92.2)	100 (79.4 to 100)	80 (56.3 to 94.3)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	20	21	18
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	36 (10.9 to 69.2)	30 (11.9 to 54.3)	10 (1.2 to 30.4)	11 (1.4 to 34.7)

M14459 (fHBP) (Day 30)	100 (71.5 to 100)	95 (75.1 to 99.87)	35 (15.4 to 59.2)	33 (13.3 to 59)
M14459 (fHBP) (Day 365)	82 (48.2 to 97.7)	60 (36.1 to 80.9)	14 (3 to 36.3)	11 (1.4 to 34.7)
M01-0240364 (NadA) (Day 1)	20 (2.5 to 55.6)	42 (20.3 to 66.5)	5 (0.13 to 24.9)	6 (0.15 to 28.7)
M01-0240364 (NadA) (Day 30)	100 (71.5 to 100)	100 (82.4 to 100)	21 (6.1 to 45.6)	28 (9.7 to 53.5)
M01-0240364 (NadA) (Day 365)	100 (71.5 to 100)	95 (74 to 99.87)	15 (3.2 to 37.9)	11 (1.4 to 34.7)
NZ98/254 (PorA) (Day 1)	9 (0.23 to 41.3)	26 (9.1 to 51.2)	5 (0.12 to 23.8)	6 (0.14 to 27.3)
NZ98/254 (PorA) (Day 30)	82 (48.2 to 97.7)	95 (74 to 99.87)	19 (5.4 to 41.9)	17 (3.6 to 41.4)
NZ98/254 (PorA) (Day 365)	45 (16.7 to 76.6)	42 (20.3 to 66.5)	19 (5.4 to 41.9)	6 (0.14 to 27.3)
M07-0241084 (NHBA) (Day 1)	64 (30.8 to 89.1)	58 (33.5 to 79.7)	19 (5.4 to 41.9)	17 (3.6 to 41.4)
M07-0241084 (NHBA) (Day 30)	91 (58.7 to 99.77)	95 (74 to 99.87)	33 (14.6 to 57)	22 (6.4 to 47.6)
M07-0241084 (NHBA) (Day 365)	82 (48.2 to 97.7)	74 (48.8 to 90.9)	29 (11.3 to 52.2)	17 (3.6 to 41.4)
H44/76 (fHBP) (Day 1)	45 (16.7 to 76.6)	30 (11.9 to 54.3)	5 (0.12 to 23.8)	6 (0.14 to 27.3)
H44/76 (fHBP) (Day 30)	100 (71.5 to 100)	100 (83.2 to 100)	58 (33.5 to 79.7)	33 (13.3 to 59)
H44/76 (fHBP) (Day 365)	82 (48.2 to 97.7)	65 (40.8 to 84.6)	19 (5.4 to 41.9)	11 (1.4 to 34.7)
5/99 (NadA) (Day 1)	89 (51.8 to 99.72)	95 (74 to 99.87)	19 (5.4 to 41.9)	17 (3.6 to 41.4)
5/99 (NadA) (Day 30)	100 (71.5 to 100)	100 (82.4 to 100)	76 (52.8 to 91.8)	83 (58.6 to 96.4)
5/99 (NadA) (Day 365)	100 (71.5 to 100)	100 (82.4 to 100)	43 (21.8 to 66)	33 (13.3 to 59)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	24 (6.8 to 49.9)			
M14459 (fHBP) (Day 30)	25 (7.3 to 52.4)			
M14459 (fHBP) (Day 365)	24 (6.8 to 49.9)			
M01-0240364 (NadA) (Day 1)	12 (1.5 to 36.4)			
M01-0240364 (NadA) (Day 30)	13 (1.6 to 38.3)			
M01-0240364 (NadA) (Day 365)	18 (3.8 to 43.4)			
NZ98/254 (PorA) (Day 1)	0 (0 to 19.5)			
NZ98/254 (PorA) (Day 30)	6 (0.16 to 30.2)			
NZ98/254 (PorA) (Day 365)	6 (0.15 to 28.7)			

M07-0241084 (NHBA) (Day 1)	35 (14.2 to 61.7)			
M07-0241084 (NHBA) (Day 30)	38 (15.2 to 64.6)			
M07-0241084 (NHBA) (Day 365)	35 (14.2 to 61.7)			
H44/76 (fHBP) (Day 1)	0 (0 to 19.5)			
H44/76 (fHBP) (Day 30)	6 (0.16 to 30.2)			
H44/76 (fHBP) (Day 365)	6 (0.15 to 28.7)			
5/99 (NadA) (Day 1)	24 (6.8 to 49.9)			
5/99 (NadA) (Day 30)	25 (7.3 to 52.4)			
5/99 (NadA) (Day 365)	18 (3.8 to 43.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.

End point title	15. Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains.[13]

End point description:

Percentage of subjects with four-fold rise in HT-hSBA titers against N. meningitidis serogroup B strains at 36 months after the primary vaccination.
Four-fold rise is defined as follows: for subjects with a pre-vaccination titer < 1:2, a post-titer of ≥ 1:8; for subjects with a pre-vaccination titer ≥ 1:2 at least a four-fold increase.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 30 and Day 365

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	22	15	20
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 30)	76 (52.8 to 91.8)	0 (0 to 15.4)	86 (57.2 to 98.2)	0 (0 to 16.8)
M14459 (fHBP) (Day 365)	24 (8.2 to 47.2)	0 (0 to 15.4)	0 (0 to 23.2)	0 (0 to 16.8)
M01-0240364 (NadA) (Day 30)	100 (83.9 to 100)	5 (0.12 to 22.8)	93 (66.1 to 99.82)	6 (0.15 to 28.7)
M01-0240364 (NadA) (Day 365)	62 (38.4 to 81.9)	5 (0.12 to 22.8)	64 (35.1 to 87.2)	6 (0.14 to 27.3)

NZ98/254 (PorA) (Day 30)	81 (58.1 to 94.6)	0 (0 to 15.4)	71 (41.9 to 91.6)	5 (0.13 to 24.9)
NZ98/254 (PorA) (Day 365)	10 (1.2 to 30.4)	0 (0 to 15.4)	14 (1.8 to 42.8)	0 (0 to 16.8)
M07-0241084 (NHBA) (Day 30)	81 (58.1 to 94.6)	0 (0 to 15.4)	93 (66.1 to 99.82)	0 (0 to 16.8)
M07-0241084 (NHBA) (Day 365)	19 (5.4 to 41.9)	0 (0 to 15.4)	0 (0 to 23.2)	0 (0 to 16.8)
H44/76 (fHBP) (Day 30)	81 (58.1 to 94.6)	5 (0.12 to 22.8)	93 (68.1 to 99.83)	0 (0 to 16.8)
H44/76 (fHBP) (Day 365)	38 (18.1 to 61.6)	0 (0 to 15.4)	20 (4.3 to 48.1)	0 (0 to 16.8)
5/99 (NadA) (Day 30)	100 (83.9 to 100)	5 (0.12 to 22.8)	93 (66.1 to 99.82)	0 (0 to 16.8)
5/99 (NadA) (Day 365)	67 (43 to 85.4)	5 (0.12 to 22.8)	86 (57.2 to 98.2)	0 (0 to 16.8)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	20	21	18
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 30)	100 (71.5 to 100)	75 (50.9 to 91.3)	15 (3.2 to 37.9)	6 (0.14 to 27.3)
M14459 (fHBP) (Day 365)	36 (10.9 to 69.2)	25 (8.7 to 49.1)	10 (1.2 to 30.4)	0 (0 to 18.5)
M01-0240364 (NadA) (Day 30)	100 (69.2 to 100)	89 (66.9 to 98.7)	16 (3.4 to 39.6)	24 (6.8 to 49.9)
M01-0240364 (NadA) (Day 365)	90 (55.5 to 99.75)	79 (54.4 to 93.9)	15 (3.2 to 37.9)	6 (0.15 to 28.7)
NZ98/254 (PorA) (Day 30)	82 (48.2 to 97.7)	63 (38.4 to 83.7)	19 (5.4 to 41.9)	6 (0.14 to 27.3)
NZ98/254 (PorA) (Day 365)	9 (0.23 to 41.3)	5 (0.13 to 26)	10 (1.2 to 30.4)	0 (0 to 18.5)
M07-0241084 (NHBA) (Day 30)	82 (48.2 to 97.7)	58 (33.5 to 79.7)	14 (3 to 36.3)	0 (0 to 18.5)
M07-0241084 (NHBA) (Day 365)	27 (6 to 61)	5 (0.13 to 26)	0 (0 to 16.1)	0 (0 to 18.5)
H44/76 (fHBP) (Day 30)	100 (71.5 to 100)	75 (50.9 to 91.3)	37 (16.3 to 61.6)	28 (9.7 to 53.5)
H44/76 (fHBP) (Day 365)	64 (30.8 to 89.1)	30 (11.9 to 54.3)	10 (1.2 to 30.4)	0 (0 to 18.5)
5/99 (NadA) (Day 30)	100 (66.4 to 100)	100 (82.4 to 100)	57 (34 to 78.2)	78 (52.4 to 93.6)
5/99 (NadA) (Day 365)	89 (51.8 to 99.72)	74 (48.8 to 90.9)	29 (11.3 to 52.2)	28 (9.7 to 53.5)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Percentage				
number (confidence interval 95%)				

M14459 (fHBP) (Day 30)	6 (0.16 to 30.2)			
M14459 (fHBP) (Day 365)	6 (0.15 to 28.7)			
M01-0240364 (NadA) (Day 30)	6 (0.16 to 30.2)			
M01-0240364 (NadA) (Day 365)	6 (0.15 to 28.7)			
NZ98/254 (PorA) (Day 30)	6 (0.16 to 30.2)			
NZ98/254 (PorA) (Day 365)	6 (0.15 to 28.7)			
M07-0241084 (NHBA) (Day 30)	6 (0.16 to 30.2)			
M07-0241084 (NHBA) (Day 365)	6 (0.15 to 28.7)			
H44/76 (fHBP) (Day 30)	6 (0.16 to 30.2)			
H44/76 (fHBP) (Day 365)	6 (0.15 to 28.7)			
5/99 (NadA) (Day 30)	6 (0.16 to 30.2)			
5/99 (NadA) (Day 365)	6 (0.15 to 28.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: 16. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

End point title	16. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.[14]

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at 24 and 36 months after the primary vaccination.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1 and Day 365

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	22	16	20
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	3.98 (1.98 to 8)	2.73 (1.44 to 5.15)	3.07 (1.26 to 7.47)	2.98 (1.38 to 6.42)

Men A (Day 365)	25 (11 to 59)	2.62 (1.39 to 4.94)	44 (18 to 105)	3.03 (1.3 to 7.06)
Men C (Day 1)	18 (8.21 to 39)	19 (7.54 to 49)	19 (8.13 to 44)	10 (5.52 to 19)
Men C (Day 365)	128 (75 to 217)	15 (5.82 to 39)	177 (102 to 305)	9.14 (4.07 to 21)
Men W (Day 1)	36 (21 to 62)	43 (24 to 79)	30 (7.82 to 112)	17 (6.88 to 43)
Men W (Day 365)	190 (133 to 272)	28 (13 to 59)	213 (135 to 337)	16 (5.58 to 47)
Men Y (Day 1)	10 (4.39 to 24)	16 (4.85 to 54)	24 (6.62 to 90)	5.39 (2.06 to 14)
Men Y (Day 365)	116 (58 to 231)	18 (5.05 to 62)	235 (147 to 376)	5.93 (1.97 to 18)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	20	20	18
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	2.27 (0.87 to 5.94)	4.22 (1.63 to 11)	6.31 (2.82 to 14)	2.49 (1.52 to 4.09)
Men A (Day 365)	54 (17 to 174)	53 (22 to 130)	34 (16 to 69)	6.52 (2.71 to 16)
Men C (Day 1)	5.2 (2.8 to 9.65)	7.83 (4.51 to 14)	7.89 (4.26 to 15)	8.45 (2.64 to 27)
Men C (Day 365)	29 (10 to 82)	32 (16 to 67)	81 (46 to 141)	72 (27 to 191)
Men W (Day 1)	25 (7.98 to 79)	23 (9.81 to 52)	28 (11 to 70)	15 (4.54 to 47)
Men W (Day 365)	80 (26 to 246)	96 (72 to 127)	172 (97 to 306)	104 (49 to 221)
Men Y (Day 1)	2.4 (1.05 to 5.47)	1.9 (1.02 to 3.55)	7.05 (3.08 to 16)	6.83 (2.11 to 22)
Men Y (Day 365)	7.17 (1.91 to 27)	20 (6.92 to 58)	193 (123 to 301)	101 (36 to 280)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	5.48 (2.18 to 14)			
Men A (Day 365)	3.54 (1.4 to 8.92)			
Men C (Day 1)	24 (9.34 to 61)			
Men C (Day 365)	24 (8.98 to 66)			
Men W (Day 1)	10 (3.53 to 30)			
Men W (Day 365)	16 (5.27 to 49)			
Men Y (Day 1)	7.03 (1.99 to 25)			

Men Y (Day 365)	9.56 (2.44 to 37)			

Statistical analyses

No statistical analyses for this end point

Secondary: 17. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

End point title	17. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.[15]

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroup B at 24 and 36 months after the primary vaccination.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1 and Day 365

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	22	16	20
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	2.69 (1.51 to 4.78)	2.94 (1.77 to 4.89)	1.54 (0.9 to 2.63)	2.01 (1.4 to 2.88)
M14459 (fHBP) (Day 365)	7.19 (3.89 to 13)	1.67 (1.07 to 2.6)	2.94 (1.49 to 5.8)	1.47 (1.07 to 2.03)
M01-0240364 (NadA) (Day 1)	2.33 (1.25 to 4.36)	3.39 (1.43 to 8.05)	2.87 (0.86 to 9.59)	1.26 (0.89 to 1.8)
M01-0240364 (NadA) (Day 365)	30 (9.54 to 93)	3.55 (1.56 to 8.07)	74 (18 to 300)	1.23 (0.91 to 1.68)
NZ98/254 (PorA) (Day 1)	1.73 (1.06 to 2.81)	2.34 (1.33 to 4.1)	1.34 (0.94 to 1.93)	1.48 (1.01 to 2.17)
NZ98/254 (PorA) (Day 365)	3.49 (2.12 to 5.74)	1.71 (1.14 to 2.57)	2.67 (1.27 to 5.61)	1.23 (0.9 to 1.69)
M07-0241084 (NHBA) (Day 1)	3.68 (2.07 to 6.54)	4.2 (2.25 to 7.85)	2.28 (1.16 to 4.48)	2.36 (1.51 to 3.7)
M07-0241084 (NHBA) (Day 365)	7.96 (4.6 to 14)	3.28 (2.16 to 4.97)	4.09 (2.3 to 7.25)	2.04 (1.43 to 2.92)
H44/76 (fHBP) (Day 1)	3.58 (1.66 to 7.71)	2.23 (1.28 to 3.9)	1.49 (0.96 to 2.33)	1.73 (0.97 to 3.1)
H44/76 (fHBP) (Day 365)	12 (5.18 to 26)	1.93 (1.2 to 3.1)	4.19 (1.93 to 9.11)	1.83 (1.07 to 3.15)
5/99 (NadA) (Day 1)	18 (9.47 to 34)	18 (9.5 to 34)	31 (12 to 85)	31 (15 to 65)
5/99 (NadA) (Day 365)	175 (79 to 385)	13 (6.07 to 29)	305 (149 to 625)	23 (11 to 47)

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	20	21	18
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	3.11 (1.74 to 5.56)	3.37 (1.95 to 5.81)	1.85 (1.13 to 3.04)	1.48 (1.03 to 2.13)
M14459 (fHBP) (Day 365)	11 (4.41 to 28)	7.12 (3.59 to 14)	2.09 (1.33 to 3.29)	1.38 (0.98 to 1.93)
M01-0240364 (NadA) (Day 1)	2.46 (0.72 to 8.4)	6.29 (2.22 to 18)	1.24 (0.79 to 1.94)	1.24 (0.88 to 1.77)
M01-0240364 (NadA) (Day 365)	303 (174 to 527)	155 (69 to 350)	1.61 (0.99 to 2.63)	1.71 (0.86 to 3.42)
NZ98/254 (PorA) (Day 1)	1.72 (0.99 to 2.98)	2.24 (1.2 to 4.17)	1.18 (0.84 to 1.66)	1.19 (0.9 to 1.58)
NZ98/254 (PorA) (Day 365)	3.28 (1.66 to 6.49)	3.77 (1.98 to 7.18)	1.65 (1.04 to 2.61)	1.19 (0.91 to 1.54)
M07-0241084 (NHBA) (Day 1)	4.1 (1.89 to 8.9)	7.35 (3.82 to 14)	2.08 (1.26 to 3.42)	2.15 (1.14 to 4.05)
M07-0241084 (NHBA) (Day 365)	10 (4.51 to 24)	11 (6.35 to 18)	2.45 (1.59 to 3.79)	1.91 (1.14 to 3.23)
H44/76 (fHBP) (Day 1)	3.45 (1.81 to 6.57)	3.43 (1.83 to 6.43)	1.34 (0.85 to 2.13)	1.51 (0.91 to 2.48)
H44/76 (fHBP) (Day 365)	21 (6 to 71)	11 (4.68 to 25)	1.96 (1.21 to 3.19)	1.92 (1.17 to 3.17)
5/99 (NadA) (Day 1)	27 (8.61 to 86)	39 (21 to 74)	2.97 (1.58 to 5.59)	1.8 (1.01 to 3.22)
5/99 (NadA) (Day 365)	587 (351 to 983)	491 (258 to 936)	6.05 (3.1 to 12)	4.23 (1.48 to 12)

End point values	1M_Pbo			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	2.55 (1.37 to 4.77)			
M14459 (fHBP) (Day 365)	2.17 (1.07 to 4.41)			
M01-0240364 (NadA) (Day 1)	1.68 (0.85 to 3.33)			
M01-0240364 (NadA) (Day 365)	2.03 (0.9 to 4.58)			
NZ98/254 (PorA) (Day 1)	1.13 (0.94 to 1.37)			
NZ98/254 (PorA) (Day 365)	1.28 (0.85 to 1.92)			
M07-0241084 (NHBA) (Day 1)	3.5 (1.57 to 7.8)			

M07-0241084 (NHBA) (Day 365)	3.92 (1.9 to 8.07)			
H44/76 (fHBP) (Day 1)	1.19 (0.97 to 1.47)			
H44/76 (fHBP) (Day 365)	1.49 (0.9 to 2.48)			
5/99 (NadA) (Day 1)	3.2 (1.44 to 7.09)			
5/99 (NadA) (Day 365)	2.45 (1 to 5.99)			

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.

End point title	18. Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y.[16]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:8 against N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV	2B_OMV	2B_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	11	20
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	38 (18.1 to 61.6)	20 (4.3 to 48.1)	30 (6.7 to 65.2)	35 (15.4 to 59.2)
Men C (Day 1)	65 (40.8 to 84.6)	71 (41.9 to 91.6)	36 (10.9 to 69.2)	58 (33.5 to 79.7)
Men W (Day 1)	95 (75.1 to 99.87)	75 (42.8 to 94.5)	82 (48.2 to 97.7)	75 (50.9 to 91.3)
Men Y (Day 1)	62 (38.4 to 81.9)	71 (41.9 to 91.6)	36 (10.9 to 69.2)	11 (1.4 to 34.7)
Men A (Day 30)	100 (83.9 to 100)	100 (78.2 to 100)	100 (69.2 to 100)	95 (75.1 to 99.87)
Men C (Day 30)	100 (80.5 to 100)	100 (69.2 to 100)	100 (59 to 100)	100 (76.8 to 100)
Men W (Day 30)	100 (81.5 to 100)	100 (78.2 to 100)	100 (71.5 to 100)	100 (81.5 to 100)
Men Y (Day 30)	100 (83.9 to 100)	100 (78.2 to 100)	82 (48.2 to 97.7)	83 (58.6 to 96.4)

Men A (Day 365)	67 (43 to 85.4)	88 (61.7 to 98.4)	90 (55.5 to 99.75)	85 (62.1 to 96.8)
Men C (Day 365)	100 (83.9 to 100)	100 (79.4 to 100)	82 (48.2 to 97.7)	95 (74 to 99.87)
Men W(Day 365)	100 (83.9 to 100)	100 (79.4 to 100)	91 (58.7 to 99.77)	100 (83.2 to 100)
Men Y (Day 365)	95 (76.2 to 99.88)	100 (79.4 to 100)	45 (16.7 to 76.6)	72 (46.5 to 90.3)

End point values	1M_OMV	1M_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	18		
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	45 (23.1 to 68.5)	12 (1.5 to 36.4)		
Men C (Day 1)	58 (33.5 to 79.7)	50 (26 to 74)		
Men W (Day 1)	82 (56.6 to 96.2)	61 (35.7 to 82.7)		
Men Y (Day 1)	55 (31.5 to 76.9)	44 (21.5 to 69.2)		
Men A (Day 30)	100 (81.5 to 100)	94 (69.8 to 99.84)		
Men C (Day 30)	100 (82.4 to 100)	88 (63.6 to 98.5)		
Men W (Day 30)	100 (80.5 to 100)	100 (79.4 to 100)		
Men Y (Day 30)	100 (83.2 to 100)	100 (80.5 to 100)		
Men A (Day 365)	85 (62.1 to 96.8)	50 (26 to 74)		
Men C (Day 365)	100 (82.4 to 100)	89 (65.3 to 98.6)		
Men W(Day 365)	100 (82.4 to 100)	100 (81.5 to 100)		
Men Y (Day 365)	100 (83.2 to 100)	89 (65.3 to 98.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis in strains of serogroup B.

End point title	19. Percentage of subjects with HT-hSBA titer ≥ 1:5 to N. meningitidis in strains of serogroup B.[17]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:5 against N. meningitidis in strains of serogroup B at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable

serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV	2B_OMV	2B_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	11	20
Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	24 (8.2 to 47.2)	7 (0.18 to 33.9)	36 (10.9 to 69.2)	30 (11.9 to 54.3)
M01-0240364 (NadA) (Day 1)	24 (8.2 to 47.2)	21 (4.7 to 50.8)	20 (2.5 to 55.6)	42 (20.3 to 66.5)
NZ98/254 (PorA) (Day 1)	19 (5.4 to 41.9)	7 (0.18 to 33.9)	9 (0.23 to 41.3)	26 (9.1 to 51.2)
M07-0241084 (NHBA) (Day 1)	38 (18.1 to 61.6)	29 (8.4 to 58.1)	64 (30.8 to 89.1)	58 (33.5 to 79.7)
H44/76 (fHBP) (Day 1)	19 (5.4 to 41.9)	13 (1.7 to 40.5)	45 (16.7 to 76.6)	30 (11.9 to 54.3)
5/99 (NadA) (Day 1)	76 (52.8 to 91.8)	86 (57.2 to 98.2)	89 (51.8 to 99.72)	95 (74 to 99.87)
M14459 (fHBP) (Day 30)	95 (76.2 to 99.88)	88 (61.7 to 98.4)	100 (71.5 to 100)	95 (75.1 to 99.87)
M01-0240364 (NadA) (Day 30)	100 (83.9 to 100)	100 (79.4 to 100)	100 (71.5 to 100)	100 (82.4 to 100)
NZ98/254 (PorA) (Day 30)	95 (76.2 to 99.88)	75 (47.6 to 92.7)	82 (48.2 to 97.7)	95 (74 to 99.87)
M07-0241084 (NHBA) (Day 30)	100 (83.9 to 100)	94 (69.8 to 99.84)	91 (58.7 to 99.77)	95 (74 to 99.87)
H44/76 (fHBP) (Day 30)	95 (76.2 to 99.88)	100 (79.4 to 100)	100 (71.5 to 100)	100 (83.2 to 100)
5/99 (NadA) (Day 30)	100 (83.9 to 100)	100 (79.4 to 100)	100 (71.5 to 100)	100 (82.4 to 100)
M14459 (fHBP) (Day 365)	57 (34 to 78.2)	38 (15.2 to 64.6)	82 (48.2 to 97.7)	60 (36.1 to 80.9)
M01-0240364 (NadA) (Day 365)	71 (47.8 to 88.7)	75 (47.6 to 92.7)	100 (71.5 to 100)	95 (74 to 99.87)
NZ98/254 (PorA) (Day 365)	29 (11.3 to 52.2)	31 (11 to 58.7)	45 (16.7 to 76.6)	42 (20.3 to 66.5)
M07-0241084 (NHBA) (Day 365)	62 (38.4 to 81.9)	50 (24.7 to 75.3)	82 (48.2 to 97.7)	74 (48.8 to 90.9)
H44/76 (fHBP) (Day 365)	76 (52.8 to 91.8)	44 (19.8 to 70.1)	82 (48.2 to 97.7)	65 (40.8 to 84.6)
5/99 (NadA) (Day 365)	95 (76.2 to 99.88)	100 (79.4 to 100)	100 (71.5 to 100)	100 (82.4 to 100)

End point values	1M_OMV	1M_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	18		

Units: Percentage				
number (confidence interval 95%)				
M14459 (fHBP) (Day 1)	10 (1.2 to 30.4)	11 (1.4 to 34.7)		
M01-0240364 (NadA) (Day 1)	5 (0.13 to 24.9)	6 (0.15 to 28.7)		
NZ98/254 (PorA) (Day 1)	5 (0.12 to 23.8)	6 (0.14 to 27.3)		
M07-0241084 (NHBA) (Day 1)	19 (5.4 to 41.9)	17 (3.6 to 41.4)		
H44/76 (fHBP) (Day 1)	5 (0.12 to 23.8)	6 (0.14 to 27.3)		
5/99 (NadA) (Day 1)	19 (5.4 to 41.9)	17 (3.6 to 41.4)		
M14459 (fHBP) (Day 30)	35 (15.4 to 59.2)	33 (13.3 to 59)		
M01-0240364 (NadA) (Day 30)	21 (6.1 to 45.6)	28 (9.7 to 53.5)		
NZ98/254 (PorA) (Day 30)	19 (5.4 to 41.9)	17 (3.6 to 41.4)		
M07-0241084 (NHBA) (Day 30)	33 (14.6 to 57)	22 (6.4 to 47.6)		
H44/76 (fHBP) (Day 30)	58 (33.5 to 79.7)	33 (13.3 to 59)		
5/99 (NadA) (Day 30)	76 (52.8 to 91.8)	83 (58.6 to 96.4)		
M14459 (fHBP) (Day 365)	14 (3 to 36.3)	11 (1.4 to 34.7)		
M01-0240364 (NadA) (Day 365)	15 (3.2 to 37.9)	11 (1.4 to 34.7)		
NZ98/254 (PorA) (Day 365)	19 (5.4 to 41.9)	6 (0.14 to 27.3)		
M07-0241084 (NHBA) (Day 365)	29 (11.3 to 52.2)	17 (3.6 to 41.4)		
H44/76 (fHBP) (Day 365)	19 (5.4 to 41.9)	11 (1.4 to 34.7)		
5/99 (NadA) (Day 365)	43 (21.8 to 66)	33 (13.3 to 59)		

Statistical analyses

No statistical analyses for this end point

Secondary: 20. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.

End point title	20. The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y.[18]

End point description:

The HT-hSBA GMTs against N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV	2B_OMV	2B_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	11	20
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	3.98 (1.98 to 8)	3.07 (1.26 to 7.47)	2.27 (0.87 to 5.94)	4.22 (1.63 to 11)
Men C (Day 1)	18 (8.21 to 39)	19 (8.13 to 44)	5.2 (2.8 to 9.65)	7.83 (4.51 to 14)
Men W (Day 1)	36 (21 to 62)	30 (7.82 to 112)	25 (7.98 to 79)	23 (9.81 to 52)
Men Y (Day 1)	10 (4.39 to 24)	24 (6.62 to 90)	2.4 (1.05 to 5.47)	1.9 (1.02 to 3.55)
Men A (Day 30)	275 (174 to 435)	348 (202 to 601)	445 (277 to 715)	428 (196 to 931)
Men C (Day 30)	737 (459 to 1183)	766 (325 to 1804)	292 (75 to 1142)	102 (57 to 181)
Men W (Day 30)	844 (535 to 1333)	890 (665 to 1190)	392 (252 to 610)	395 (321 to 487)
Men Y (Day 30)	444 (257 to 768)	748 (463 to 1208)	48 (14 to 157)	54 (17 to 171)
Men A (Day 365)	25 (11 to 59)	44 (18 to 105)	54 (17 to 174)	53 (22 to 130)
Men C (Day 365)	128 (75 to 217)	177 (102 to 305)	29 (10 to 82)	32 (16 to 67)
Men W (Day 365)	190 (133 to 272)	213 (135 to 337)	80 (26 to 246)	96 (72 to 127)
Men Y (Day 365)	116 (58 to 231)	235 (147 to 376)	7.17 (1.91 to 27)	20 (6.92 to 58)

End point values	1M_OMV	1M_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	18		
Units: Titers				
geometric mean (confidence interval 95%)				
Men A (Day 1)	6.31 (2.82 to 14)	2.49 (1.52 to 4.09)		
Men C (Day 1)	7.89 (4.26 to 15)	8.45 (2.64 to 27)		
Men W (Day 1)	28 (11 to 70)	15 (4.54 to 47)		
Men Y (Day 1)	7.05 (3.08 to 16)	6.83 (2.11 to 22)		
Men A (Day 30)	140 (82 to 239)	46 (23 to 91)		
Men C (Day 30)	322 (186 to 556)	307 (118 to 795)		
Men W (Day 30)	620 (354 to 1085)	360 (169 to 765)		

Men Y (Day 30)	662 (424 to 1032)	404 (201 to 811)		
Men A (Day 365)	34 (16 to 69)	6.52 (2.71 to 16)		
Men C (Day 365)	81 (46 to 141)	72 (27 to 191)		
Men W (Day 365)	172 (96 to 306)	104 (49 to 221)		
Men Y (Day 365)	193 (123 to 301)	101 (36 to 280)		

Statistical analyses

No statistical analyses for this end point

Secondary: 21. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.

End point title	21. The HT-hSBA GMTs against N. meningitidis strains of serogroup B.[19]

End point description:

The HT-hSBA GMTs against N. meningitidis strains of serogroups B at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV	2B_OMV	2B_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	11	20
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	2.69 (1.51 to 4.78)	1.54 (0.9 to 2.63)	3.11 (1.74 to 5.56)	3.37 (1.95 to 5.81)
M01-0240364 (NadA) (Day 1)	2.33 (1.25 to 4.36)	2.87 (0.86 to 9.59)	2.46 (0.72 to 8.4)	6.29 (2.22 to 18)
NZ98/254 (PorA) (Day 1)	1.73 (1.06 to 2.81)	1.34 (0.94 to 1.93)	1.72 (0.99 to 2.98)	2.24 (1.2 to 4.17)
M07-0241084 (NHBA) (Day 1)	3.68 (2.07 to 6.54)	2.28 (1.16 to 4.48)	4.1 (1.89 to 8.9)	7.35 (3.82 to 14)
H44/76 (fHBP) (Day 1)	3.58 (1.66 to 7.71)	1.49 (0.96 to 2.33)	3.45 (1.81 to 6.57)	3.43 (1.83 to 6.43)
5/99 (NadA) (Day 1)	18 (9.47 to 34)	31 (12 to 85)	27 (8.61 to 86)	39 (21 to 74)
M14459 (fHBP) (Day 30)	39 (21 to 70)	20 (10 to 39)	56 (27 to 117)	35 (21 to 60)
M01-0240364 (NadA) (Day 30)	679 (352 to 1310)	903 (463 to 1761)	1336 (810 to 2202)	1261 (746 to 2131)
NZ98/254 (PorA) (Day 30)	32 (19 to 52)	15 (5.93 to 36)	17 (6.22 to 45)	28 (17 to 47)
M07-0241084 (NHBA) (Day 30)	59 (36 to 98)	36 (20 to 64)	68 (33 to 142)	66 (35 to 124)
H44/76 (fHBP) (Day 30)	104 (59 to 184)	57 (32 to 102)	132 (64 to 271)	79 (40 to 153)

5/99 (NadA) (Day 30)	1147 (665 to 1980)	1598 (864 to 2956)	2205 (1560 to 3117)	2816 (1856 to 4273)
M14459 (fHBP) (Day 365)	7.19 (3.89 to 13)	2.94 (1.49 to 5.8)	11 (4.41 to 28)	7.12 (3.59 to 14)
M01-0240364 (NadA) (Day 365)	30 (9.54 to 93)	74 (18 to 300)	303 (174 to 527)	155 (69 to 350)
NZ98/254 (PorA) (Day 365)	3.49 (2.12 to 5.74)	2.67 (1.27 to 5.61)	3.28 (1.66 to 6.49)	3.77 (1.98 to 7.18)
M07-0241084 (NHBA) (Day 365)	7.96 (4.6 to 14)	4.09 (2.3 to 7.25)	10 (4.51 to 24)	11 (6.35 to 18)
H44/76 (fHBP) (Day 365)	12 (5.18 to 26)	4.19 (1.93 to 9.11)	21 (6 to 71)	11 (4.68 to 25)
5/99 (NadA) (Day 365)	175 (79 to 385)	305 (149 to 625)	587 (351 to 983)	491 (258 to 936)

End point values	1M_OMV	1M_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	18		
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (fHBP) (Day 1)	1.85 (1.13 to 3.04)	1.48 (1.03 to 2.13)		
M01-0240364 (NadA) (Day 1)	1.24 (0.79 to 1.94)	1.24 (0.88 to 1.77)		
NZ98/254 (PorA) (Day 1)	1.18 (0.84 to 1.66)	1.19 (0.9 to 1.58)		
M07-0241084 (NHBA) (Day 1)	2.08 (1.26 to 3.42)	2.15 (1.14 to 4.05)		
H44/76 (fHBP) (Day 1)	1.34 (0.85 to 2.13)	1.51 (0.91 to 2.48)		
5/99 (NadA) (Day 1)	2.97 (1.58 to 5.59)	1.8 (1.01 to 3.22)		
M14459 (fHBP) (Day 30)	3.44 (2.05 to 5.75)	2.71 (1.56 to 4.7)		
M01-0240364 (NadA) (Day 30)	2.68 (1.15 to 6.25)	3.66 (1.21 to 11)		
NZ98/254 (PorA) (Day 30)	2.48 (1.31 to 4.69)	1.62 (0.96 to 2.74)		
M07-0241084 (NHBA) (Day 30)	3.26 (1.75 to 6.06)	2.24 (1.14 to 4.38)		
H44/76 (fHBP) (Day 30)	5.27 (2.54 to 11)	3.89 (1.79 to 8.47)		
5/99 (NadA) (Day 30)	28 (11 to 67)	29 (10 to 80)		
M14459 (fHBP) (Day 365)	2.09 (1.33 to 3.29)	1.38 (0.98 to 1.93)		
M01-0240364 (NadA) (Day 365)	1.61 (0.99 to 2.63)	1.71 (0.86 to 3.42)		
NZ98/254 (PorA) (Day 365)	1.65 (1.04 to 2.61)	1.19 (0.91 to 1.54)		
M07-0241084 (NHBA) (Day 365)	2.45 (1.59 to 3.79)	1.91 (1.14 to 3.23)		
H44/76 (fHBP) (Day 365)	1.96 (1.21 to 3.19)	1.92 (1.17 to 3.17)		
5/99 (NadA) (Day 365)	6.05 (3.1 to 12)	4.23 (1.48 to 12)		

Statistical analyses

No statistical analyses for this end point

Secondary: 22. Percentage of subjects with Ht-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y at 12 months after booster vaccination.

End point title	22. Percentage of subjects with Ht-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y at 12 months after booster vaccination.[20]

End point description:

Percentage of subjects with HT-hSBA titer ≥ 1:8 to N. meningitidis serogroups A, C, W, Y at Day 1, Day 30 (one month) and Day 365 (12 months) after the administration of MenABCWY booster vaccination in this study.
Analysis was done on FAS Day 365 (Persistence of Booster). All subjects in the enrolled population who were randomized, actually received the study vaccination in V102_03E1 and provided an evaluable serum sample at Day 365.

End point type	Secondary

End point timeframe:

Day 1, Day 30 and Day 365

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The scope of this endpoint was descriptive, no statistical analyses were conducted.

End point values	2OMV_OMV	2qOMV_qOMV	2B_OMV	2B_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21	16	11	20
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	38 (18.1 to 61.6)	20 (4.3 to 48.1)	30 (6.7 to 65.2)	35 (15.4 to 59.2)
Men C (Day 1)	65 (40.8 to 84.6)	71 (41.9 to 91.6)	36 (10.9 to 69.2)	58 (33.5 to 79.7)
Men W (Day 1)	95 (75.1 to 99.87)	75 (42.8 to 94.5)	82 (48.2 to 97.7)	75 (50.9 to 91.3)
Men Y (Day 1)	62 (38.4 to 81.9)	71 (41.9 to 91.6)	36 (10.9 to 69.2)	11 (1.4 to 34.7)
Men A (Day 30)	100 (83.9 to 100)	100 (78.2 to 100)	100 (69.2 to 100)	95 (75.1 to 99.87)
Men C (Day 30)	100 (80.5 to 100)	100 (69.2 to 100)	100 (59 to 100)	100 (76.8 to 100)
Men W (Day 30)	100 (81.5 to 100)	100 (78.2 to 100)	100 (71.5 to 100)	100 (81.5 to 100)
Men Y (Day 30)	100 (83.9 to 100)	100 (78.2 to 100)	82 (48.2 to 97.7)	83 (58.6 to 96.4)
Men A (Day 365)	67 (43 to 85.4)	88 (61.7 to 98.4)	90 (55.5 to 99.75)	85 (62.1 to 96.8)
Men C (Day 365)	100 (83.9 to 100)	100 (79.4 to 100)	82 (48.2 to 97.7)	95 (74 to 99.87)

Men W (Day 365)	100 (83.9 to 100)	100 (79.4 to 100)	91 (58.7 to 99.77)	100 (83.2 to 100)
Men Y (Day 365)	95 (76.2 to 99.88)	100 (79.4 to 100)	45 (16.7 to 76.6)	72 (46.5 to 90.3)

End point values	1M_OMV	1M_qOMV		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	18		
Units: Percentage				
number (confidence interval 95%)				
Men A (Day 1)	45 (23.1 to 68.5)	12 (1.5 to 36.4)		
Men C (Day 1)	58 (33.5 to 79.7)	50 (26 to 74)		
Men W (Day 1)	82 (56.6 to 96.2)	61 (35.7 to 82.7)		
Men Y (Day 1)	55 (31.5 to 76.9)	44 (21.5 to 69.2)		
Men A (Day 30)	100 (81.5 to 100)	94 (69.8 to 99.84)		
Men C (Day 30)	100 (82.4 to 100)	88 (63.6 to 98.5)		
Men W (Day 30)	100 (80.5 to 100)	100 (79.4 to 100)		
Men Y (Day 30)	100 (83.2 to 100)	100 (80.5 to 100)		
Men A (Day 365)	85 (62.1 to 96.8)	50 (26 to 74)		
Men C (Day 365)	100 (82.4 to 100)	89 (65.3 to 98.6)		
Men W (Day 365)	100 (82.4 to 100)	100 (81.5 to 100)		
Men Y (Day 365)	100 (83.2 to 100)	89 (65.3 to 98.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: 23. Number of subjects with solicited local and systemic AEs following booster vaccination in this study.

End point title	23. Number of subjects with solicited local and systemic AEs following booster vaccination in this study.

End point description:

Number of subjects reporting solicited local and systemic AEs after receiving a booster dose of MenABCWY vaccine or placebo.
Analysis was done on the Solicited Safety Set, i.e. all exposed subjects who provide post vaccination solicited adverse event data.

End point type	Secondary

End point timeframe:

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

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	24	17	23
Units: Subjects				
Any local	23	7	15	8
Injection site pain	20	6	14	7
Injection site induration	7	2	5	2
Injection site erythema	11	2	7	3
Any systemic	12	9	12	6
Chills	3	1	0	0
Nausea	0	2	3	1
Fatigue	9	6	8	2
Myalgia	6	2	5	0
Arthralgia	3	2	3	1
Loss of appetite	2	1	4	2
Headache	7	6	8	3
Rash	0	0	1	0
Body temperature (> 38 °C)	2	0	0	1
Use of analgesics/antipyretics	0	0	1	0

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Subjects				
Any local	11	18	19	17
Injection site pain	11	17	19	17
Injection site induration	9	6	7	4
Injection site erythema	6	7	6	9
Any systemic	5	10	15	10
Chills	1	2	5	1
Nausea	3	5	4	5
Fatigue	5	8	11	6
Myalgia	1	4	8	4
Arthralgia	0	2	4	2
Loss of appetite	1	3	8	3
Headache	5	4	12	5
Rash	0	1	1	2
Body temperature (> 38 °C)	0	0	0	0
Use of analgesics/antipyretics	0	0	0	0

End point values	1M_Pbo	2B_Pbo		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	6		
Units: Subjects				
Any local	5	1		
Injection site pain	4	1		
Injection site induration	1	0		
Injection site erythema	2	0		
Any systemic	5	1		
Chills	1	0		
Nausea	1	0		
Fatigue	5	0		
Myalgia	1	0		
Arthralgia	3	0		
Loss of appetite	2	0		
Headache	2	1		
Rash	0	0		
Body temperature (> 38 °C)	0	0		
Use of analgesics/antipyretics	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: 24. Number of subjects with unsolicited (any AEs and possibly related AEs) following booster vaccination in this study.

End point title	24. Number of subjects with unsolicited (any AEs and possibly related AEs) following booster vaccination in this study.

End point description:

Number of subjects reporting unsolicited AEs (any AEs and at least possibly related AEs) after receiving a booster dose of MenABCWY vaccine or placebo from Day 1 to Day 30.
Analysis was done on the Unsolicited Safety Set. All subjects in the exposed population who provided information about post-vaccination AEs or safety records at Day 30.

End point type	Secondary

End point timeframe:

Day 1 through Day 30

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	24	17	23
Units: Subjects				
Any AEs	6	4	5	2
At least possibly related	3	1	3	0

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Subjects				
Any AEs	3	7	6	5
At least possibly related	2	3	2	3

End point values	1M_Pbo	2B_Pbo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	6		
Units: Subjects				
Any AEs	4	1		
At least possibly related	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: 25. Number of subjects with unsolicited AEs following booster vaccination in this study.

End point title	25. Number of subjects with unsolicited AEs following booster vaccination in this study.

End point description:

Number of subjects reporting any serious unsolicited AEs (SAEs), possibly related SAEs, medically attended AEs, unsolicited AEs leading to withdrawal and deaths after receiving a booster dose of MenABCWY vaccine or placebo, are reported for the entire study period.
Analysis was done on the Unsolicited Safety Set. All subjects in the exposed population who provided information about post-vaccination AEs or safety records at Day 365.

End point type	Secondary

End point timeframe:

Day 1 through Day 365

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	24	17	23
Units: Subjects				
Any SAEs	0	0	1	1
At Least Possibly related SAEs	0	0	0	0
NOCD	0	3	2	0
Medically attended AEs	12	10	12	9
AEs leading to withdrawal	0	0	0	0
Deaths	0	0	0	0

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Subjects				
Any SAEs	0	1	0	1
At Least Possibly related SAEs	0	0	0	0
NOCD	0	1	1	1
Medically attended AEs	6	9	13	11
AEs leading to withdrawal	0	0	0	0
Deaths	0	0	0	0

End point values	1M_Pbo	2B_Pbo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	6		
Units: Subjects				
Any SAEs	1	0		
At Least Possibly related SAEs	0	0		
NOCD	1	0		
Medically attended AEs	11	1		
AEs leading to withdrawal	0	0		
Deaths	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: 26. Number of subjects with unsolicited AEs leading to New Onset Chronic Disease (NOCD) before study vaccination.

End point title	26. Number of subjects with unsolicited AEs leading to New Onset Chronic Disease (NOCD) before study vaccination.

End point description:

Number of subjects reporting New Onset Chronic Disease (NOCD),from the end of the primary parental study V102_03 up to Day 1 visit in V102_03E1 study, is reported. (Any NOCD AEs: NOCD V102_03 vs. NOCD- Day 1, Pre vaccination, V102_03E1).
Analysis was done on the all enrolled set population. All screened subjects who have been enrolled (ie, attended the first clinic visit and received a subject ID).

End point type	Secondary

End point timeframe:

From primary parent study completion up to Day 1 in this study.

End point values	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV	2qOMV_Pbo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	25	17	24
Units: Subjects				
NOCD (SOC/PT) Day 1, V102_03E1)	2	4	0	1

End point values	2B_OMV	2B_qOMV	1M_OMV	1M_qOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	21	21	19
Units: Subjects				
NOCD (SOC/PT) Day 1, V102_03E1)	0	2	2	2

End point values	1M_Pbo	2B_Pbo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	7		
Units: Subjects				
NOCD (SOC/PT) Day 1, V102_03E1)	1	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs between Day 1 (from 30 minutes) to Day 7; any unsolicited AEs from Day 1 (from 30 minutes) to Day 30, and SAEs, medically attended AEs, AEs leading to withdrawal, death and NOCD from Day 1 to Day 365.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	2OMV_OMV

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one booster dose of same vaccine in this study.

Reporting group title	2OMV_Pbo

Reporting group description:

Subjects who previously received two doses of MenABCWY + OMV in the parent study, received one dose of saline solution in this study.

Reporting group title	2qOMV_qOMV

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one booster dose of same vaccine in this study.

Reporting group title	2qOMV_Pbo

Reporting group description:

Subjects who previously received two doses of MenABCWY + ¼ OMV in the parent study, received one dose of saline solution in this study.

Reporting group title	2B_OMV

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + OMV in this study.

Reporting group title	2B_qOMV

Reporting group description:

Subjects who previously received two doses of rMenB + OMV in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Reporting group title	1M_OMV

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + OMV in this study.

Reporting group title	1M_qOMV

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of MenABCWY + ¼ OMV in this study.

Reporting group title	1M_Pbo

Reporting group description:

Subjects who previously received one dose of MenACWY in the parent study, received one dose of saline solution in this study.

Reporting group title	2B_Pbo

Reporting group description: -

Serious adverse events	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Facial bones fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	2qOMV_Pbo	2B_OMV	2B_qOMV
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	1 / 21 (4.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Facial bones fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	0 / 21 (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
Limb injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	1M_OMV	1M_qOMV	1M_Pbo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 19 (5.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Facial bones fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (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
Nervous system disorders			
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	2B_Pbo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Facial bones fracture			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	2OMV_OMV	2OMV_Pbo	2qOMV_qOMV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 27 (92.59%)	16 / 24 (66.67%)	16 / 17 (94.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	3 / 27 (11.11%)	1 / 24 (4.17%)	0 / 17 (0.00%)
occurrences (all)	3	2	0
Fatigue			
subjects affected / exposed	9 / 27 (33.33%)	8 / 24 (33.33%)	8 / 17 (47.06%)
occurrences (all)	9	11	9
Induration			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	11 / 27 (40.74%)	2 / 24 (8.33%)	7 / 17 (41.18%)
occurrences (all)	12	2	8
Injection site induration			
subjects affected / exposed	7 / 27 (25.93%)	2 / 24 (8.33%)	6 / 17 (35.29%)
occurrences (all)	7	2	6
Injection site pain			
subjects affected / exposed	21 / 27 (77.78%)	7 / 24 (29.17%)	14 / 17 (82.35%)
occurrences (all)	23	7	14

Pyrexia			
subjects affected / exposed	2 / 27 (7.41%)	1 / 24 (4.17%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Vaccination site erythema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	2 / 27 (7.41%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	3	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	2 / 27 (7.41%)	1 / 24 (4.17%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Post vaccination syndrome			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	8 / 27 (29.63%)	6 / 24 (25.00%)	8 / 17 (47.06%)
occurrences (all)	8	6	9
Syncope			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Photophobia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Myopia			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 27 (0.00%)	2 / 24 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	1 / 27 (3.70%)	2 / 24 (8.33%)	3 / 17 (17.65%)
occurrences (all)	1	2	4
Tooth impacted			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 27 (7.41%)	1 / 24 (4.17%)	0 / 17 (0.00%)
occurrences (all)	2	1	0
Dermatitis contact			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 27 (14.81%)	2 / 24 (8.33%)	3 / 17 (17.65%)
occurrences (all)	4	2	3
Myalgia			
subjects affected / exposed	6 / 27 (22.22%)	2 / 24 (8.33%)	5 / 17 (29.41%)
occurrences (all)	6	2	5
Myositis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Scoliosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Costochondritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 27 (0.00%)	2 / 24 (8.33%)	2 / 17 (11.76%)
occurrences (all)	0	2	2
Influenza			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	1	0	1
Lice infestation			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 27 (0.00%)	2 / 24 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	2	0
Pharyngitis			
subjects affected / exposed	1 / 27 (3.70%)	2 / 24 (8.33%)	2 / 17 (11.76%)
occurrences (all)	1	2	2
Pneumonia			
subjects affected / exposed	2 / 27 (7.41%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Sinusitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	2
Tonsillitis			
subjects affected / exposed	2 / 27 (7.41%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	2	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	0	2
Viral infection			
subjects affected / exposed	2 / 27 (7.41%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	3	0	0
Acute sinusitis			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 27 (3.70%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	0 / 17 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1
Decreased appetite			
subjects affected / exposed	2 / 27 (7.41%)	1 / 24 (4.17%)	4 / 17 (23.53%)
occurrences (all)	3	2	5
Obesity			
subjects affected / exposed	0 / 27 (0.00%)	2 / 24 (8.33%)	0 / 17 (0.00%)
occurrences (all)	0	2	0

Vitamin D deficiency			
subjects affected / exposed	0 / 27 (0.00%)	0 / 24 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	0	1

Non-serious adverse events	2qOMV_Pbo	2B_OMV	2B_qOMV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 24 (58.33%)	11 / 11 (100.00%)	19 / 21 (90.48%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	2 / 21 (9.52%)
occurrences (all)	0	3	2
Fatigue			
subjects affected / exposed	2 / 24 (8.33%)	5 / 11 (45.45%)	8 / 21 (38.10%)
occurrences (all)	2	5	9
Induration			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	3 / 24 (12.50%)	7 / 11 (63.64%)	7 / 21 (33.33%)
occurrences (all)	3	7	7
Injection site induration			
subjects affected / exposed	3 / 24 (12.50%)	10 / 11 (90.91%)	7 / 21 (33.33%)
occurrences (all)	3	11	9
Injection site pain			
subjects affected / exposed	7 / 24 (29.17%)	11 / 11 (100.00%)	18 / 21 (85.71%)
occurrences (all)	7	11	19
Pyrexia			

subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Body temperature increased			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Post vaccination syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	3 / 24 (12.50%)	5 / 11 (45.45%)	4 / 21 (19.05%)
occurrences (all)	3	7	5
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Photophobia			

subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 24 (4.17%)	3 / 11 (27.27%)	5 / 21 (23.81%)
occurrences (all)	1	3	5
Tooth impacted			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed	0 / 24 (0.00%)	2 / 11 (18.18%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	2 / 21 (9.52%)
occurrences (all)	1	0	2
Myalgia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	4 / 21 (19.05%)
occurrences (all)	0	1	4
Myositis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Scoliosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			

subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lice infestation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 24 (4.17%)	1 / 11 (9.09%)	2 / 21 (9.52%)
occurrences (all)	1	3	2
Pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 24 (4.17%)	1 / 11 (9.09%)	1 / 21 (4.76%)
occurrences (all)	1	1	1
Viral infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			

subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Croup infectious			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Herpes virus infection			
subjects affected / exposed	1 / 24 (4.17%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	1	1	0
Onychomycosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 11 (9.09%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 24 (8.33%)	1 / 11 (9.09%)	3 / 21 (14.29%)
occurrences (all)	2	1	3
Obesity			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Vitamin D deficiency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 11 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	1M_OMV	1M_qOMV	1M_Pbo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 21 (95.24%)	17 / 19 (89.47%)	15 / 19 (78.95%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Chills			
subjects affected / exposed	6 / 21 (28.57%)	1 / 19 (5.26%)	1 / 19 (5.26%)
occurrences (all)	6	1	1
Fatigue			
subjects affected / exposed	11 / 21 (52.38%)	6 / 19 (31.58%)	5 / 19 (26.32%)
occurrences (all)	11	7	7
Induration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	7 / 21 (33.33%)	9 / 19 (47.37%)	2 / 19 (10.53%)
occurrences (all)	8	9	2
Injection site induration			
subjects affected / exposed	11 / 21 (52.38%)	9 / 19 (47.37%)	1 / 19 (5.26%)
occurrences (all)	13	9	1
Injection site pain			
subjects affected / exposed	19 / 21 (90.48%)	17 / 19 (89.47%)	6 / 19 (31.58%)
occurrences (all)	19	19	6
Pyrexia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site pruritus			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0

Body temperature increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Post vaccination syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Head injury			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness postural			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	14 / 21 (66.67%)	5 / 19 (26.32%)	2 / 19 (10.53%)
occurrences (all)	15	5	2
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye disorders			
Photophobia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Myopia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 21 (19.05%)	5 / 19 (26.32%)	1 / 19 (5.26%)
occurrences (all)	4	6	1
Tooth impacted			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Dermatitis contact			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	3 / 21 (14.29%)	2 / 19 (10.53%)	0 / 19 (0.00%)
occurrences (all)	3	2	0
Dermatitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Urticaria			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 21 (19.05%)	2 / 19 (10.53%)	3 / 19 (15.79%)
occurrences (all)	4	2	4
Myalgia			
subjects affected / exposed	8 / 21 (38.10%)	4 / 19 (21.05%)	1 / 19 (5.26%)
occurrences (all)	8	4	1
Myositis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Scoliosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Costochondritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Joint effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Influenza			

subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lice infestation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Pharyngitis			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	2
Pneumonia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 21 (9.52%)	2 / 19 (10.53%)	1 / 19 (5.26%)
occurrences (all)	2	2	2
Viral infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Conjunctivitis			

subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
Croup infectious			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Herpes virus infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Otitis media			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	2 / 21 (9.52%)	0 / 19 (0.00%)	1 / 19 (5.26%)
occurrences (all)	2	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 21 (0.00%)	1 / 19 (5.26%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Viral pharyngitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 19 (5.26%)	1 / 19 (5.26%)
occurrences (all)	3	2	1
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	8 / 21 (38.10%)	4 / 19 (21.05%)	2 / 19 (10.53%)
occurrences (all)	9	4	3
Obesity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Vitamin D deficiency			
subjects affected / exposed	0 / 21 (0.00%)	0 / 19 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	2B_Pbo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Essential hypertension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Induration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injection site induration			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Pyrexia			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vaccination site erythema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injection site pruritus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vaccination site pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Breast mass			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Body temperature increased subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Injury, poisoning and procedural complications Limb injury subjects affected / exposed occurrences (all) Post vaccination syndrome subjects affected / exposed occurrences (all) Concussion subjects affected / exposed occurrences (all) Head injury subjects affected / exposed occurrences (all) Joint dislocation subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Nervous system disorders Dizziness postural subjects affected / exposed occurrences (all) Headache subjects affected / exposed occurrences (all) Syncope subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0 1 / 6 (16.67%) 2 0 / 6 (0.00%) 0		
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0		
Eye disorders Photophobia			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Myopia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tooth impacted			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Urticaria			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all) Myositis subjects affected / exposed occurrences (all) Scoliosis subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Joint effusion subjects affected / exposed occurrences (all) Temporomandibular joint syndrome subjects affected / exposed occurrences (all)	 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Influenza	 0 / 6 (0.00%) 0 		

subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Lice infestation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Sinusitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Acute sinusitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Conjunctivitis				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Croup infectious			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Herpes virus infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Onychomycosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Viral pharyngitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Obesity			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 May 2013	• Modified schedule for booster dose administration. • To ensure an adequate number of subjects in each treatment group, the sample size and randomisation ratios per group have been adjusted. • Collection of data related to NOCD at the time of study entry and during the trial was added. • Updated Protocol to new Protocol Template. All Novartis approved language on topics relating to Diary Cards, safety data collection, visit procedures, protocol deviations, withdrawal from study criteria, and AE reporting are incorporated into the current protocol amendment 1.0, version 2.0 dated 09 May 13.
19 November 2013	Increased window time for Day 1 visit (for U.S. study sites).
06 May 2014	• Increased window time for Day 1 visit (extended to all study sites). • Added approach for interim and final analyses. Added administration of Bexsero for Group IVc outside the scope of study per request of Polish Ethics Committee. • Defined "End of Study" to align with Novartis standards. • Added public database posting and AE/SAE reporting requirements to align with Novartis standards.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported