



Clinical trial results:

Phase 2, Observer-Blind, Controlled, Randomized, Multi-Center Extension Study to Evaluate Safety, Tolerability and Immunogenicity of a Third Dose of One of Four Different Formulations of rMenB + MenACWY in Adolescents Who Previously Received the Same Study Vaccines

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2014-005014-36
Trial protocol	Outside EU/EEA
Global end of trial date	06 July 2012

Results information

Result version number	v2 (current)
This version publication date	17 June 2016
First version publication date	22 March 2015
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	V102_02E1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01367158
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccines and Diagnostics S.r.l.
Sponsor organisation address	Via Fiorentina 1, Siena, Italy, 53100
Public contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l., RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines and Diagnostics S.r.l., RegistryContactVaccinesUS@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-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	15 January 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	06 July 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 2, Observer-Blind, Controlled, Randomized, Multi-Center Extension Study to Evaluate Safety, Tolerability and Immunogenicity of a Third Dose of One of Four Different Formulations of rMenB + MenACWY in Adolescents Who Previously Received the Same Study vaccines.

Protection of trial subjects:

This clinical study was designed, implemented and reported in accordance with the International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), with applicable local regulations (including European Directive 2001/20/EC, US Code of Federal Regulations Title 21, and Japanese Ministry of Health, Labor, and Welfare), and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 July 2011
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Chile: 44
Country: Number of subjects enrolled	Colombia: 104
Country: Number of subjects enrolled	Panama: 292
Worldwide total number of subjects	440
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	18
Adolescents (12-17 years)	374
Adults (18-64 years)	48
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled from 6 study centres in Panama, 3 in Columbia and 2 in Chile

Pre-assignment

Screening details:

Subjects previously allocated to groups I–V of the primary study were to be randomized in a 1:2 ratio to receive, either a third dose of the same vaccine as in the primary study (NCT number: NCT01210885) or a dose of tetanus, diphtheria and acellular pertussis vaccine (Tdap) respectively. Subjects in group VI received only Tdap in this 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	Investigator, Carer, Subject

Blinding implementation details:

Study subjects and personnel assessing the safety and eligibility of subjects will remain blinded to the treatment assigned in this study.

Arms

Are arms mutually exclusive?	Yes
Arm title	3ABCWY

Arm description:

Two doses of MenABCWY vaccine (no outer membrane vesicle {OMV}) in the primary study and one dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (rMenB (no OMV)+MenACWY lyophilized)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of injectable solution

Arm title	2ABCWY
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Arm description:

Two doses of MenABCWY vaccine (no OMV) in the primary study and one dose of Tdap in the current study.

Arm type	Active comparator
Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL of injectable solution.

Arm title	3ABx2CWY
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Arm description:

Two doses of MenABx2CWY vaccine in the primary study and one dose of the same vaccine in the current study.

Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (rMenBx2doses (no OMV)+MenACWY lyophilized)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1.0 mL of injectable solution.	
Arm title	2ABx2CWY
Arm description: Two doses of MenABx2CWY vaccine in the primary study and one dose of Tdap in the current study.	
Arm type	Active comparator
Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution.	
Arm title	3ABCWY+OMV
Arm description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Arm type	Experimental
Investigational medicinal product name	Combined MenABCWY vaccine (rMenB + OMV liquid suspension + MenACWY lyophilized)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution.	
Arm title	2ABCWY+OMV
Arm description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of Tdap in the current study.	
Arm type	Active comparator
Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution.	
Arm title	3ABCWYqOMV
Arm description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Arm type	Experimental

Investigational medicinal product name	Combined MenABCWY vaccine (rMenB + 1/4 OMV liquid suspension + MenACWY lyophilized)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution	
Arm title	2ABCWYqOMV
Arm description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of Tdap in the current study.	
Arm type	Active comparator
Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution	
Arm title	Men 3B
Arm description: Two doses of rMenB vaccine in the primary study and one dose of the same vaccine in the current study.	
Arm type	Experimental
Investigational medicinal product name	Novartis rMenB vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution.	
Arm title	Men 2B
Arm description: Two doses of rMenB vaccine in the primary study and one dose of Tdap in the current study.	
Arm type	Active comparator
Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5 mL of injectable solution	
Arm title	1ACWY
Arm description: One dose of MenACWY vaccine followed by one dose of placebo in the primary study and one dose of Tdap in the current study.	
Arm type	Active comparator

Investigational medicinal product name	Tdap
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL of injectable solution	

Number of subjects in period 1	3ABCWY	2ABCWY	3ABx2CWY
Started	25	49	24
Completed	25	46	23
Not completed	0	3	1
Consent withdrawn by subject	-	2	1
Lost to follow-up	-	-	-
Protocol deviation	-	1	-

Number of subjects in period 1	2ABx2CWY	3ABCWY+OMV	2ABCWY+OMV
Started	49	25	48
Completed	48	23	46
Not completed	1	2	2
Consent withdrawn by subject	-	2	-
Lost to follow-up	1	-	2
Protocol deviation	-	-	-

Number of subjects in period 1	3ABCWYqOMV	2ABCWYqOMV	Men 3B
Started	25	49	23
Completed	25	47	23
Not completed	0	2	0
Consent withdrawn by subject	-	1	-
Lost to follow-up	-	1	-
Protocol deviation	-	-	-

Number of subjects in period 1	Men 2B	1ACWY
Started	50	73
Completed	50	72
Not completed	0	1
Consent withdrawn by subject	-	-
Lost to follow-up	-	1
Protocol deviation	-	-

Baseline characteristics

Reporting groups	
Reporting group title	3ABCWY
Reporting group description: Two doses of MenABCWY vaccine (no outer membrane vesicle {OMV}) in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWY
Reporting group description: Two doses of MenABCWY vaccine (no OMV) in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABx2CWY
Reporting group description: Two doses of MenABx2CWY vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABx2CWY
Reporting group description: Two doses of MenABx2CWY vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABCWY+OMV
Reporting group description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWY+OMV
Reporting group description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABCWYqOMV
Reporting group description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWYqOMV
Reporting group description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	Men 3B
Reporting group description: Two doses of rMenB vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	Men 2B
Reporting group description: Two doses of rMenB vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	1ACWY
Reporting group description: One dose of MenACWY vaccine followed by one dose of placebo in the primary study and one dose of Tdap in the current study.	

Reporting group values	3ABCWY	2ABCWY	3ABx2CWY
Number of subjects	25	49	24
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0

Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	1	0	1
Adolescents (12-17 years)	21	44	22
Adults (18-64 years)	3	5	1
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	14.3	14.2	14.4
standard deviation	± 2.2	± 2	± 2.1
Gender categorical			
Units: Subjects			
Female	16	29	14
Male	9	20	10

Reporting group values	2ABx2CWY	3ABCWY+OMV	2ABCWY+OMV
Number of subjects	49	25	48
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	2	1	2
Adolescents (12-17 years)	42	18	44
Adults (18-64 years)	5	6	2
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	14.4	14.9	14.2
standard deviation	± 2.1	± 2.6	± 2.1
Gender categorical			
Units: Subjects			
Female	27	12	26
Male	22	13	22

Reporting group values	3ABCWYqOMV	2ABCWYqOMV	Men 3B
Number of subjects	25	49	23
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	1	4	3
Adolescents (12-17 years)	22	41	16

Adults (18-64 years)	2	4	4
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	14.3	14.4	14.8
standard deviation	± 2	± 2.1	± 2.5
Gender categorical			
Units: Subjects			
Female	14	19	11
Male	11	30	12

Reporting group values	Men 2B	1ACWY	Total
Number of subjects	50	73	440
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	2	1	18
Adolescents (12-17 years)	42	62	374
Adults (18-64 years)	6	10	48
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	15	14.8	
standard deviation	± 2	± 2.1	-
Gender categorical			
Units: Subjects			
Female	25	39	232
Male	25	34	208

End points

End points reporting groups

Reporting group title	3ABCWY
Reporting group description: Two doses of MenABCWY vaccine (no outer membrane vesicle {OMV}) in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWY
Reporting group description: Two doses of MenABCWY vaccine (no OMV) in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABx2CWY
Reporting group description: Two doses of MenABx2CWY vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABx2CWY
Reporting group description: Two doses of MenABx2CWY vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABCWY+OMV
Reporting group description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWY+OMV
Reporting group description: Two doses of MenABCWY+OMV vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	3ABCWYqOMV
Reporting group description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	2ABCWYqOMV
Reporting group description: Two doses of MenABCWY+1/4OMV vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	Men 3B
Reporting group description: Two doses of rMenB vaccine in the primary study and one dose of the same vaccine in the current study.	
Reporting group title	Men 2B
Reporting group description: Two doses of rMenB vaccine in the primary study and one dose of Tdap in the current study.	
Reporting group title	1ACWY
Reporting group description: One dose of MenACWY vaccine followed by one dose of placebo in the primary study and one dose of Tdap in the current study.	
Subject analysis set title	Enrolled Set
Subject analysis set type	Intention-to-treat
Subject analysis set description: All subjects who signed an informed consent, underwent screening procedures, and were randomized.	
Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis
Subject analysis set description: All exposed subjects with adverse event data.	
Subject analysis set title	MITT Set- Month 6

Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects who received all the relevant doses of vaccine correctly; provided evaluable serum samples at the relevant time points; had no major protocol deviations .	
Subject analysis set title	MITT Set- Month 7
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects who received all the relevant doses of vaccine correctly; provided evaluable serum samples at the relevant time points; had no major protocol deviations.	
Subject analysis set title	MITT Set- Month 12
Subject analysis set type	Modified intention-to-treat
Subject analysis set description:	
Subjects who received all the relevant doses of vaccine correctly; provided evaluable serum samples at the relevant time points; had no major protocol deviations.	

Primary: Percentages of Subjects With hSBA $\geq 1:8$ Against Serogroups A, C, W and Y at One Month After the Third Vaccination With Either One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Percentages of Subjects With hSBA $\geq 1:8$ Against Serogroups A, C, W and Y at One Month After the Third Vaccination With Either One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^{[1][2]}
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End point description:

Antibody response was measured as the percentage of subjects with human serum bactericidal assay (hSBA) titers $\geq 1:8$ and associated 95% CI, directed against to N meningitidis serogroups A, C, W, and Y at 6 months following first vaccine during the parent study NCT01210885 and one month after third vaccination (Month 7). MITT Month 7.

End point type	Primary
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End point timeframe:

At month 6 and month 7

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: No statistical analyses for this end point.

[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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Percentage of subjects				
number (confidence interval 95%)				
Ser. A - month 6 (N=23,24,24,25,23,69)	52 (31 to 73)	79 (58 to 93)	75 (53 to 90)	68 (46 to 85)
Ser. A - month 7 (N=24,24,21,25,22,71)	100 (86 to 100)	100 (86 to 100)	100 (84 to 100)	100 (86 to 100)
Ser. C - month 6 (N=22,24,24,24,21,70)	100 (85 to 100)	96 (79 to 100)	100 (86 to 100)	100 (86 to 100)
Ser. C - month 7 (N=23,24,23,25,22,72)	100 (85 to 100)	100 (86 to 100)	100 (85 to 100)	100 (86 to 100)
Ser. W - month 6 (N=24,24,25,24,22,69)	100 (86 to 100)	96 (79 to 100)	100 (86 to 100)	100 (86 to 100)
Ser. W - month 7 (N=23,24,21,25,21,72)	100 (85 to 100)	100 (86 to 100)	100 (84 to 100)	100 (86 to 100)
Ser. Y - month 6 (N=24,24,24,25,23,72)	96 (79 to 100)	100 (86 to 100)	96 (79 to 100)	92 (74 to 99)

Ser. Y - month 7 (N=25,24,24,25,22,72)	100 (86 to 100)	96 (79 to 100)	100 (86 to 100)	100 (86 to 100)
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End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	72		
Units: Percentage of subjects				
number (confidence interval 95%)				
Ser. A - month 6 (N=23,24,24,25,23,69)	35 (16 to 57)	55 (43 to 67)		
Ser. A - month 7 (N=24,24,21,25,22,71)	91 (71 to 99)	58 (45 to 69)		
Ser. C - month 6 (N=22,24,24,24,21,70)	33 (15 to 57)	76 (64 to 85)		
Ser. C - month 7 (N=23,24,23,25,22,72)	73 (50 to 89)	68 (56 to 79)		
Ser. W - month 6 (N=24,24,25,24,22,69)	55 (32 to 76)	97 (90 to 100)		
Ser. W - month 7 (N=23,24,21,25,21,72)	90 (70 to 99)	96 (88 to 99)		
Ser. Y - month 6 (N=24,24,24,25,23,72)	4 (0 to 22)	85 (74 to 92)		
Ser. Y - month 7 (N=25,24,24,25,22,72)	14 (3 to 35)	85 (74 to 92)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentages of Subjects With hSBA $\geq 1:5$ Against Serogroup B Test Strains at One Month After Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Percentages of Subjects With hSBA $\geq 1:5$ Against Serogroup B Test Strains at One Month After Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^{[3][4]}
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End point description:

Antibody response was measured as the percentage of subjects with human serum bactericidal assay (hSBA) titers $\geq 1:5$ and associated 95% CI, directed against to Serogroup B Test Strains at 6 months following first vaccine during the parent study NCT01210885 and one month after third vaccination (Month 7).

End point type	Primary
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End point timeframe:

At month 6 and month 7

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: No statistical analyses for this end point.

[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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Percentage of subjects				
number (confidence interval 95%)				
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	40 (21 to 61)	46 (26 to 67)	52 (31 to 72)	29 (13 to 51)
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	92 (74 to 99)	96 (79 to 100)	96 (79 to 100)	92 (74 to 99)
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	96 (80 to 100)	100 (86 to 100)	96 (79 to 100)	100 (86 to 100)
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	100 (86 to 100)	100 (86 to 100)	100 (86 to 100)	100 (86 to 100)
NZ98/254(PorA) - month 6 (N=25,24,24,25,23,72)	12 (3 to 31)	8 (1 to 27)	29 (13 to 51)	12 (3 to 31)
NZ98/254(PorA) - month 7 (N=25,24,24,25,23,73)	20 (7 to 41)	29 (13 to 51)	88 (68 to 97)	76 (55 to 91)
M14459(fHBP) - month 6 (N=25,24,25,25,23,71)	24 (9 to 45)	25 (10 to 47)	32 (15 to 54)	16 (5 to 36)
M14459(fHBP) - month 7 (N=25,24,23,25,22,73)	80 (59 to 93)	79 (58 to 93)	87 (66 to 97)	88 (69 to 97)
M07-0241084(NHBA) - month 6 (N=25,23,23,25,23,70)	20 (7 to 41)	35 (16 to 57)	39 (20 to 61)	52 (31 to 72)
M07-0241084(NHBA) - month 7 (N=25,23,22,25,21,72)	68 (46 to 85)	61 (39 to 80)	95 (77 to 100)	92 (74 to 99)
M01-0240364(NadA) - month 6 (N=25,21,24,24,21,71)	16 (5 to 36)	38 (18 to 62)	25 (10 to 47)	33 (16 to 55)
M01-0240364(NadA) - month 7 (N=24,23,24,25,23,71)	96 (79 to 100)	100 (85 to 100)	100 (86 to 100)	96 (80 to 100)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Percentage of subjects				
number (confidence interval 95%)				
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	35 (16 to 57)	3 (0 to 10)		
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	91 (71 to 99)	4 (1 to 12)		
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	100 (85 to 100)	15 (8 to 26)		
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	100 (85 to 100)	16 (9 to 27)		
NZ98/254(PorA) - month 6 (N=25,24,24,25,23,72)	9 (1 to 28)	0 (0 to 5)		
NZ98/254(PorA) - month 7 (N=25,24,24,25,23,73)	17 (5 to 39)	1 (0.035 to 7)		
M14459(fHBP) - month 6 (N=25,24,25,25,23,71)	17 (5 to 39)	6 (2 to 14)		
M14459(fHBP) - month 7 (N=25,24,23,25,22,73)	64 (41 to 83)	8 (3 to 17)		
M07-0241084(NHBA) - month 6 (N=25,23,23,25,23,70)	30 (13 to 53)	30 (20 to 42)		
M07-0241084(NHBA) - month 7 (N=25,23,22,25,21,72)	62 (38 to 82)	29 (19 to 41)		

M01-0240364(NadA) - month 6 (N=25,21,24,24,21,71)	33 (15 to 57)	4 (1 to 12)		
M01-0240364(NadA) - month 7 (N=24,23,24,25,23,71)	96 (78 to 100)	4 (1 to 12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMT) for N Meningitidis Serogroups A, C, W and Y at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Geometric Mean Titers (GMT) for N Meningitidis Serogroups A, C, W and Y at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[5]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers against N meningitidis Serogroups A, C, W and Y at One of Four MenABCWY Formulations or rMenB at 6 months following first vaccine during the parent study NCT01210885 and one month after third vaccination (Month 7).

End point type	Secondary
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End point timeframe:

At month 6 and month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 6 (N=23,24,24,25,23,69)	15 (6.66 to 33)	44 (20 to 96)	31 (14 to 68)	21 (9.53 to 44)
Ser. A - month 7 (N=24,24,21,25,22,71)	247 (120 to 509)	322 (157 to 659)	242 (113 to 521)	274 (136 to 553)
Ser. C - month 6 (N=22,24,24,24,21,70)	211 (125 to 355)	153 (93 to 251)	168 (102 to 278)	137 (83 to 224)
Ser. C - month 7 (N=23,24,23,25,22,72)	796 (472 to 1343)	716 (430 to 1193)	670 (397 to 1130)	634 (385 to 1044)
Ser. W - month 6 (N=24,24,25,24,22,69)	189 (116 to 305)	184 (144 to 296)	202 (127 to 324)	164 (102 to 263)
Ser. W - month 7 (N=23,24,21,25,21,72)	710 (442 to 1143)	695 (441 to 1096)	929 (570 to 1512)	684 (438 to 1069)
Ser. Y - month 6 (N=24,24,24,25,23,72)	203 (111 to 372)	233 (128 to 425)	158 (86 to 289)	129 (72 to 233)
Ser. Y - month 7 (N=25,24,24,25,22,72)	695 (385 to 1255)	629 (346 to 1144)	619 (339 to 1129)	432 (241 to 776)

End point values	Men 3B	1ACWY		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	72		
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 6 (N=23,24,24,25,23,69)	4.52 (2.02 to 10)	21 (13 to 34)		
Ser. A - month 7 (N=24,24,21,25,22,71)	135 (64 to 287)	22 (14 to 33)		
Ser. C - month 6 (N=22,24,24,24,21,70)	4.54 (2.66 to 7.75)	25 (18 to 34)		
Ser. C - month 7 (N=23,24,23,25,22,72)	31 (18 to 53)	19 (14 to 26)		
Ser. W - month 6 (N=24,24,25,24,22,69)	11 (6.67 to 18)	128 (95 to 173)		
Ser. W - month 7 (N=23,24,21,25,21,72)	126 (77 to 207)	130 (98 to 172)		
Ser. Y - month 6 (N=24,24,24,25,23,72)	1.72 (0.93 to 3.18)	97 (67 to 140)		
Ser. Y - month 7 (N=25,24,24,25,22,72)	2.64 (1.41 to 4.96)	85 (59 to 122)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Ratio (GMR) for (95%CI) for N Meningitidis Serogroups A, C, W and Y at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Geometric Mean Ratio (GMR) for (95%CI) for N Meningitidis Serogroups A, C, W and Y at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[6]
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End point description:

Antibody response was measured as Geometric Mean Ratio (95% CI), against N meningitidis Serogroups A, C, W and Y at One Month After the Third Vaccination (month 7) With One of Four MenABCWY Formulations or rMenB.

End point type	Secondary
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End point timeframe:

At month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A (N=22,24,21,25,22,68)	15 (8.88 to 25)	7.53 (4.58 to 12)	10 (6.1 to 18)	14 (8.37 to 22)
Ser. C (N=21,24,22,24,20,70)	3.43 (2.59 to 4.54)	4.63 (3.56 to 6.02)	3.85 (2.92 to 5.06)	5.01 (3.85 to 6.5)

Ser. W (N=23,24,21,24,20,69)	3.42 (2.41 to 4.85)	3.66 (2.62 to 5.12)	3.98 (2.78 to 5.69)	4.05 (2.9 to 5.66)
Ser. Y (N=24,24,23,25,22,71)	3.33 (2.31 to 4.79)	2.68 (1.87 to 3.85)	4.45 (3.06 to 6.45)	3.32 (2.33 to 4.73)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	72		
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A (N=22,24,21,25,22,68)	34 (20 to 57)	1.05 (0.77 to 1.43)		
Ser. C (N=21,24,22,24,20,70)	8.41 (6.31 to 11)	0.75 (0.64 to 0.89)		
Ser. W (N=23,24,21,24,20,69)	11 (7.55 to 16)	1.01 (0.82 to 1.24)		
Ser. Y (N=24,24,23,25,22,71)	1.46 (1 to 2.14)	0.81 (0.65 to 1.02)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT for N Meningitidis Against Serogroup B Test Strains at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	GMT for N Meningitidis Against Serogroup B Test Strains at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[7]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers Against Serogroup B Test Strains at 6 months following first vaccine during the parent study NCT01210885 and one month after third vaccination (Month 7) with One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 6 and month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	5.9 (3.07 to 11)	6.88 (3.56 to 13)	12 (6.14 to 23)	5.25 (2.71 to 10)

H44/76 (fHbp) - month 7 (N=25,24,24,24,25,22,73)	109 (60 to 201)	154 (83 to 285)	181 (97 to 336)	114 (62 to 208)
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	78 (52 to 118)	122 (80 to 186)	46 (30 to 71)	84 (56 to 127)
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	546 (365 to 817)	740 (492 to 1112)	665 (441 to 1002)	527 (354 to 786)
NZ98/254(PorA) - month 6 (N=25,24,24,25,23,72)	1.96 (1.29 to 3)	1.85 (1.21 to 2.85)	3.47 (2.26 to 5.35)	1.89 (1.24 to 2.88)
NZ98/254(PorA) - month 7 (N=25,24,24,25,23,73)	2.37 (1.5 to 3.74)	3.26 (2.06 to 5.17)	24 (15 to 37)	12 (7.57 to 19)
M14459(fHBP) - month 6 (N=25,24,25,25,23,71)	2.71 (1.72 to 4.27)	3.29 (2.08 to 5.21)	4.49 (2.85 to 7.06)	2.34 (1.49 to 3.67)
M14459(fHBP) - month 7 (N=25,24,23,25,22,73)	16 (10 to 27)	27 (17 to 44)	45 (27 to 75)	20 (13 to 33)
M07-0241084(NHBA) - month 6 (N=25,23,23,25,23,70)	3.37 (1.98 to 5.73)	3.66 (2.12 to 6.34)	6.92 (3.99 to 12)	6.45 (3.81 to 11)
M07-0241084(NHBA) - month 7 (N=25,23,22,25,21,72)	12 (7.07 to 21)	9.48 (5.37 to 17)	38 (21 to 69)	25 (15 to 44)
M01-0240364(NadA) - month 6 (N=25,21,24,24,21,71)	4.62 (2.15 to 9.95)	9.98 (4.37 to 23)	6.95 (3.19 to 15)	7.44 (3.44 to 16)
M01-0240364(NadA) - month 7 (N=24,23,24,25,23,71)	311 (152 to 637)	533 (259 to 1098)	385 (188 to 786)	286 (143 to 573)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	6.42 (3.27 to 13)	1.18 (1.01 to 1.37)		
H44/76 (fHbp) - month 7 (N=25,24,24,24,25,22,73)	109 (57 to 209)	1.21 (1.04 to 1.4)		
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	152 (99 to 234)	1.74 (1.36 to 2.22)		
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	832 (548 to 1263)	1.93 (1.5 to 2.48)		
NZ98/254(PorA) - month 6 (N=25,24,24,25,23,72)	1.81 (1.17 to 2.81)	1.15 (1.05 to 1.25)		
NZ98/254(PorA) - month 7 (N=25,24,24,25,23,73)	2.64 (1.65 to 4.23)	1.2 (1.07 to 1.33)		
M14459(fHBP) - month 6 (N=25,24,25,25,23,71)	2.48 (1.55 to 3.97)	1.28 (1.11 to 1.49)		
M14459(fHBP) - month 7 (N=25,24,23,25,22,73)	12 (7.07 to 20)	1.28 (1.1 to 1.49)		
M07-0241084(NHBA) - month 6 (N=25,23,23,25,23,70)	3.32 (1.91 to 5.75)	2.99 (2.16 to 4.14)		
M07-0241084(NHBA) - month 7 (N=25,23,22,25,21,72)	9.73 (5.33 to 18)	3.03 (2.22 to 4.15)		
M01-0240364(NadA) - month 6 (N=25,21,24,24,21,71)	7.21 (3.15 to 17)	1.18 (1 to 1.39)		
M01-0240364(NadA) - month 7 (N=24,23,24,25,23,71)	474 (229 to 980)	1.18 (1 to 1.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMR for (95%CI) for N Meningitidis Against Serogroup B Test Strains at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	GMR for (95%CI) for N Meningitidis Against Serogroup B Test Strains at One Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[8]
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End point description:

Antibody response was measured as Geometric Mean Ratio (95% CI), against Serogroup B Test Strains at One Month After the Third Vaccination (month 7) with One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) (N=25,24,24,24,22,72)	18 (12 to 29)	22 (14 to 36)	14 (8.88 to 23)	22 (14 to 36)
5/99 (NadA) (N=25,24,23,25,23,72)	6.96 (5.15 to 9.42)	6.04 (4.45 to 8.21)	14 (11 to 20)	6.25 (4.63 to 8.44)
NZ98/254 (PorA) (N=25,24,23,25,23,72)	1.21 (0.87 to 1.67)	1.76 (1.26 to 2.45)	6.56 (4.67 to 9.2)	6.29 (4.55 to 8.69)
M14459 (fHBP) (N=25,24,23,25,22,71)	5.99 (4.11 to 8.73)	8.1 (5.54 to 12)	9.08 (6.14 to 13)	8.58 (5.91 to 12)
M07-0241084 (NHBA) (N=25,22,20,25,21,69)	3.61 (2.57 to 5.09)	2.46 (1.71 to 3.54)	5.18 (3.53 to 7.58)	3.92 (2.8 to 5.51)
M01-0240364 (NadA) (N=24,20,23,24,21,69)	65 (37 to 114)	50 (27 to 92)	65 (37 to 116)	40 (23 to 71)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) (N=25,24,24,24,22,72)	16 (9.83 to 26)	1.03 (0.98 to 1.08)		
5/99 (NadA) (N=25,24,23,25,23,72)	5.47 (4 to 7.48)	1.12 (0.93 to 1.36)		
NZ98/254 (PorA) (N=25,24,23,25,23,72)	1.45 (1.04 to 2.04)	1.05 (0.95 to 1.15)		
M14459 (fHBP) (N=25,24,23,25,22,71)	4.37 (2.93 to 6.53)	1.01 (0.91 to 1.11)		

M07-0241084 (NHBA) (N=25,22,20,25,21,69)	2.75 (1.89 to 4.01)	1.01 (0.91 to 1.12)		
M01-0240364 (NadA) (N=24,20,23,24,21,69)	66 (36 to 120)	1 (0.97 to 1.04)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With Seroresponse Against N Meningitidis Serogroups A, C, W and Y at 1 Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Percentages of Subjects With Seroresponse Against N Meningitidis Serogroups A, C, W and Y at 1 Month After the Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[9]
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End point description:

Antibody response was measured as the percentage of subjects with seroresponse Against N meningitidis Serogroups A, C, W and Y, after the third vaccination (month 7) with One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo. Seroresponse to N meningitidis serogroups A, C, W and Y is defined as: For subjects with a prevaccination (month 6) hSBA <1:4, a postvaccination hSBA ≥1:8; For subjects with a prevaccination (month 6) hSBA ≥1:4, an increase in hSBA titer of at least four times the prevaccination titer.

End point type	Secondary
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End point timeframe:

At month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	23	25
Units: Percentage of Subjects				
number (confidence interval 95%)				
Ser. A (N=22,24,21,25,22,68)	59 (36 to 79)	67 (45 to 84)	67 (43 to 85)	72 (51 to 88)
Ser. C (N=21,24,22,24,20,70)	48 (26 to 70)	54 (33 to 74)	59 (36 to 79)	67 (45 to 84)
Ser. W (N=23,24,21,24,20,69)	35 (16 to 57)	38 (19 to 59)	48 (26 to 70)	58 (37 to 78)
Ser. Y (N=24,24,23,25,22,71)	29 (13 to 51)	38 (19 to 59)	43 (23 to 66)	32 (15 to 54)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	71		
Units: Percentage of Subjects				
number (confidence interval 95%)				
Ser. A (N=22,24,21,25,22,68)	82 (60 to 95)	3 (0 to 10)		
Ser. C (N=21,24,22,24,20,70)	60 (36 to 81)	0 (0 to 5)		
Ser. W (N=23,24,21,24,20,69)	60 (36 to 81)	3 (0 to 10)		
Ser. Y (N=24,24,23,25,22,71)	5 (0 to 23)	0 (0 to 5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With 4-fold Increase in hSBA Titers Against Serogroup B Test Strains at One Month After Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo

End point title	Percentages of Subjects With 4-fold Increase in hSBA Titers Against Serogroup B Test Strains at One Month After Third Vaccination With One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo ^[10]
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End point description:

Antibody response was measured as the percentage of subjects with 4-fold Increase in human serum bactericidal assay (hSBA) titers and associated 95% CI, Against Serogroup B Test Strains at One Month After Third Vaccination (month 7) with One of Four MenABCWY Formulations, rMenB or MenACWY/Placebo (compared to month 6 values).

End point type	Secondary
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End point timeframe:

At month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	24	25
Units: Percentage of subjects				
number (confidence interval 95%)				
H44/76 (fHbp) (N=25,24,24,24,22,72)	80 (59 to 93)	88 (68 to 97)	83 (63 to 95)	88 (68 to 97)
5/99 (NadA) (N=25,24,23,25,23,72)	80 (59 to 93)	67 (45 to 84)	83 (61 to 95)	76 (55 to 91)
NZ98/254 (PorA) (N=25,24,23,25,23,72)	4 (0 to 20)	17 (5 to 37)	61 (39 to 80)	44 (24 to 65)
M14459 (fHBP) (N=25,24,23,25,22,71)	56 (35 to 76)	54 (33 to 74)	65 (43 to 84)	52 (31 to 72)
M07-0241084 (NHBA) (N=25,22,20,25,21,69)	36 (18 to 57)	23 (8 to 45)	60 (36 to 81)	44 (24 to 65)
M01-0240364 (NadA) (N=24,20,23,24,21,69)	88 (68 to 97)	80 (56 to 94)	83 (61 to 95)	79 (58 to 93)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	72		
Units: Percentage of subjects				
number (confidence interval 95%)				
H44/76 (fHbp) (N=25,24,24,24,22,72)	73 (50 to 89)	0 (0 to 5)		

5/99 (NadA) (N=25,24,23,25,23,72) NZ98/254 (PorA) (N=25,24,23,25,23,72) M14459 (fHBP) (N=25,24,23,25,22,71) M07-0241084 (NHBA) (N=25,22,20,25,21,69) M01-0240364 (NadA) (N=24,20,23,24,21,69)	57 (34 to 77) 17 (5 to 39) 50 (28 to 72) 29 (11 to 52) 90 (70 to 99)	3 (0 to 10) 1 (0.035 to 7) 1 (0.036 to 8) 0 (0 to 5) 0 (0 to 5)		
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Statistical analyses

No statistical analyses for this end point

Secondary: GMT for N Meningitidis Serogroups A, C, W and Y at Month 0 Through Month 12 Following Vaccination at Month 0, Month 2 With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMT for N Meningitidis Serogroups A, C, W and Y at Month 0 Through Month 12 Following Vaccination at Month 0, Month 2 With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo ^[11]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers Against N meningitidis Serogroups A, C, W and Y after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, and after 6, 7 and 12 months of the first vaccination in the parent study (months 6, 7 and 12) with One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At months 0, 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	2ABCWY	2ABx2CWY	2ABCWY+OMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	48	49
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 0 (N=49,49,48,48,50,73)	1.65 (1.32 to 2.07)	1.41 (1.13 to 1.76)	1.38 (1.1 to 1.73)	1.2 (0.96 to 1.51)
Ser. A - month 1 (N=48,48,47,49,50,70)	61 (35 to 107)	61 (35 to 107)	49 (28 to 86)	37 (21 to 65)
Ser. A - month 3 (N=49,48,47,48,50,72)	162 (106 to 249)	206 (134 to 316)	183 (118 to 282)	169 (109 to 262)
Ser. A - month 6 (N=46,46,48,44,49,69)	28 (16 to 49)	44 (25 to 78)	21 (12 to 36)	24 (14 to 44)
Ser. A - month 7 (N=48,47,46,49,50,71)	24 (14 to 39)	28 (17 to 46)	17 (9.94 to 28)	17 (10 to 29)
Ser. A - month 12 (N=43,44,45,46,50,71)	10 (5.69 to 18)	9.73 (5.6 to 17)	8.88 (5.09 to 15)	8.08 (4.64 to 14)
Ser C - month 0 (N=49,49,48,47,50,72)	4.9 (3.37 to 7.13)	4.66 (3.21 to 6.75)	6.08 (4.17 to 8.86)	5.75 (3.92 to 8.43)

Ser. C - month 1 (N=48,48,48,48,50,71)	51 (33 to 80)	116 (75 to 180)	99 (64 to 155)	101 (64 to 159)
Ser. C - month 3 (N=49,47,46,48,50,71)	340 (252 to 460)	501 (370 to 680)	338 (248 to 461)	380 (278 to 520)
Ser. C - month 6 (N=46,48,47,48,49,70)	133 (94 to 189)	186 (133 to 261)	117 (83 to 165)	157 (111 to 223)
Ser. C - month 7 (N=48,47,46,49,50,72)	110 (78 to 156)	153 (108 to 217)	88 (61 to 126)	128 (90 to 183)
Ser. C - month 12 (N=44,46,46,46,50,72)	55 (38 to 81)	66 (45 to 95)	45 (31 to 65)	72 (49 to 105)
Ser W - month 0 (N=49,48,48,47,50,73)	19 (11 to 33)	21 (12 to 36)	29 (17 to 50)	24 (14 to 42)
Ser. W - month 1 (N=48,48,47,48,49,72)	163 (113 to 237)	243 (168 to 352)	173 (119 to 252)	233 (160 to 341)
Ser. W - month 3 (N=49,46,47,48,50,72)	370 (290 to 472)	514 (400 to 661)	349 (272 to 448)	435 (338 to 559)
Ser. W - month 6 (N=44,47,45,45,43,69)	202 (144 to 284)	196 (141 to 272)	143 (102 to 200)	194 (138 to 274)
Ser. W - month 7 (N=46,47,45,47,45,72)	173 (125 to 240)	167 (121 to 230)	118 (85 to 164)	168 (121 to 234)
Ser. W - month 12 (N=45,45,45,43,46,69)	119 (82 to 174)	113 (77 to 164)	83 (57 to 120)	109 (73 to 161)
Ser Y - month 0 (N=49,48,48,49,50,73)	5.1 (3.69 to 7.05)	4.84 (3.5 to 6.7)	5.6 (4.04 to 7.77)	4.98 (3.6 to 6.91)
Ser. Y - month 1 (N=48,48,48,49,49,73)	98 (66 to 145)	119 (80 to 177)	76 (51 to 113)	92 (62 to 136)
Ser. Y - month 3 (N=49,48,47,49,50,73)	214 (162 to 281)	283 (215 to 374)	195 (147 to 258)	226 (172 to 298)
Ser. Y - month 6 (N=48,48,48,48,49,72)	206 (134 to 315)	249 (162 to 382)	138 (90 to 212)	154 (100 to 237)
Ser. Y - month 7 (N=46,48,46,49,50,72)	180 (116 to 278)	213 (139 to 327)	100 (65 to 155)	127 (83 to 194)
Ser. Y - month 12 (N=45,47,45,46,50,70)	88 (55 to 141)	112 (71 to 178)	55 (34 to 88)	75 (47 to 121)

End point values	Men 2B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	73		
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 0 (N=49,49,48,48,50,73)	1.34 (1.07 to 1.67)	1.43 (1.18 to 1.72)		
Ser. A - month 1 (N=48,48,47,49,50,70)	2.96 (1.71 to 5.13)	107 (66 to 172)		
Ser. A - month 3 (N=49,48,47,48,50,72)	44 (29 to 68)	36 (25 to 52)		
Ser. A - month 6 (N=46,46,48,44,49,69)	4.22 (2.43 to 7.33)	20 (12 to 32)		
Ser. A - month 7 (N=48,47,46,49,50,71)	3.18 (1.95 to 5.19)	21 (13 to 31)		
Ser. A - month 12 (N=43,44,45,46,50,71)	2.21 (1.31 to 3.75)	14 (9.03 to 22)		
Ser C - month 0 (N=49,49,48,47,50,72)	8 (5.53 to 12)	4.96 (3.61 to 6.81)		
Ser. C - month 1 (N=48,48,48,48,50,71)	8.76 (5.63 to 14)	75 (51 to 109)		

Ser. C - month 3 (N=49,47,46,48,50,71)	17 (12 to 22)	45 (35 to 58)		
Ser. C - month 6 (N=46,48,47,48,49,70)	6.77 (4.82 to 9.52)	23 (17 to 31)		
Ser. C - month 7 (N=48,47,46,49,50,72)	5.53 (3.9 to 7.84)	18 (13 to 24)		
Ser. C - month 12 (N=44,46,46,46,50,72)	6.03 (4.19 to 8.69)	14 (10 to 19)		
Ser W - month 0 (N=49,48,48,47,50,73)	31 (18 to 52)	24 (15 to 38)		
Ser. W - month 1 (N=48,48,47,48,49,72)	29 (20 to 42)	210 (154 to 287)		
Ser. W - month 3 (N=49,46,47,48,50,72)	140 (110 to 179)	166 (135 to 204)		
Ser. W - month 6 (N=44,47,45,45,43,69)	15 (11 to 21)	117 (88 to 154)		
Ser. W - month 7 (N=46,47,45,47,45,72)	13 (9.72 to 19)	121 (93 to 159)		
Ser. W - month 12 (N=45,45,45,43,46,69)	11 (7.81 to 17)	75 (55 to 103)		
Ser Y - month 0 (N=49,48,48,49,50,73)	6.52 (4.73 to 8.99)	7.07 (5.38 to 9.29)		
Ser. Y - month 1 (N=48,48,48,49,49,73)	5.6 (3.77 to 8.32)	92 (66 to 128)		
Ser. Y - month 3 (N=49,48,47,49,50,73)	4.7 (3.58 to 6.18)	72 (57 to 91)		
Ser. Y - month 6 (N=48,48,48,48,49,72)	1.93 (1.26 to 2.95)	84 (58 to 120)		
Ser. Y - month 7 (N=46,48,46,49,50,72)	2.05 (1.34 to 3.13)	75 (52 to 108)		
Ser. Y - month 12 (N=45,47,45,46,50,70)	1.59 (1.01 to 2.5)	47 (31 to 69)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMR for N Meningitidis Serogroups A, C, W and Y at Month 0 Through Month 12 Following Vaccination at Month 0, Month 2 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMR for N Meningitidis Serogroups A, C, W and Y at Month 0 Through Month 12 Following Vaccination at Month 0, Month 2 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo ^[12]
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End point description:

Antibody response was measured as Geometric Mean Ratios (95%CI) Against N meningitidis Serogroups A, C, W and Y after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, after 6, 7 and 12 months of the first vaccination (months 6, 7 and 12) with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	2ABCWY	2ABx2CWY	2ABCWY+OMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	48	49
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A - month 1 (N=48,48,47,48,50,70)	41 (23 to 73)	45 (26 to 80)	36 (20 to 65)	30 (17 to 53)
Ser. A - month 3 (N=49,48,47,47,50,72)	107 (68 to 168)	150 (95 to 235)	135 (85 to 214)	137 (86 to 217)
Ser. A - month 6 (N=46,46,48,44,49,69)	19 (11 to 34)	32 (18 to 57)	15 (8.77 to 27)	20 (11 to 35)
Ser. A - month 7 (N=48,47,46,48,50,71)	16 (9.83 to 27)	21 (12 to 34)	12 (7.36 to 21)	14 (8.22 to 23)
Ser. A - month 12 (N=43,44,45,45,50,71)	6.97 (3.93 to 12)	7.18 (4.11 to 13)	6.61 (3.77 to 12)	6.42 (3.67 to 11)
Ser. C - month 1 (N=48,48,48,47,50,70)	11 (6.83 to 19)	26 (16 to 43)	19 (12 to 31)	20 (12 to 33)
Ser. C - month 3 (N=49,47,46,46,50,70)	72 (47 to 110)	114 (74 to 175)	60 (39 to 93)	71 (45 to 110)
Ser. C - month 6 (N=46,48,47,46,49,69)	29 (19 to 45)	41 (27 to 63)	22 (14 to 34)	31 (20 to 47)
Ser. C - month 7 (N=48,47,46,47,50,71)	24 (16 to 37)	33 (21 to 51)	16 (10 to 25)	25 (16 to 38)
Ser. C - month 12 (N=44,46,46,44,50,71)	12 (7.82 to 19)	16 (10 to 24)	8.88 (5.7 to 14)	15 (9.57 to 24)
Ser. W - month 1 (N=48,47,47,46,49,72)	9.2 (5.41 to 16)	13 (7.42 to 21)	7.41 (4.34 to 13)	10 (6.1 to 18)
Ser. W - month 3 (N=49,45,47,46,50,72)	20 (11 to 34)	27 (15 to 48)	12 (6.7 to 21)	19 (11 to 35)
Ser. W - month 6 (N=44,46,45,43,43,69)	11 (6.33 to 20)	9.75 (5.64 to 17)	5.44 (3.11 to 9.52)	9.75 (5.51 to 17)
Ser. W - month 7 (N=46,46,45,45,45,72)	9.21 (5.2 to 16)	8.17 (4.64 to 14)	4.84 (2.72 to 8.62)	7.94 (4.44 to 14)
Ser. W - month 12 (N=45,44,45,42,46,69)	7.33 (4.08 to 13)	6.54 (3.62 to 12)	3.52 (1.95 to 6.33)	4.83 (2.62 to 8.92)
Ser. Y - month 1 (N=48,47,48,49,49,73)	21 (13 to 32)	26 (17 to 40)	15 (9.89 to 24)	20 (13 to 31)
Ser. Y - month 3 (N=49,47,47,49,50,73)	44 (30 to 63)	59 (41 to 85)	37 (25 to 54)	47 (33 to 68)
Ser. Y - month 6 (N=48,47,48,48,49,72)	44 (27 to 71)	56 (34 to 91)	27 (16 to 44)	33 (20 to 54)
Ser. Y - month 7 (N=46,47,46,49,50,72)	37 (22 to 61)	45 (27 to 74)	19 (11 to 31)	26 (16 to 43)
Ser. Y - month 12 (N=45,46,45,46,50,70)	18 (11 to 31)	25 (15 to 42)	10 (6.14 to 18)	16 (9.64 to 28)

End point values	Men 2B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	73		
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A - month 1 (N=48,48,47,48,50,70)	2.25 (1.28 to 3.93)	78 (48 to 127)		

Ser. A - month 3 (N=49,48,47,47,50,72)	34 (21 to 52)	26 (18 to 38)		
Ser. A - month 6 (N=46,46,48,44,49,69)	3.19 (1.82 to 5.59)	15 (9.12 to 24)		
Ser. A - month 7 (N=48,47,46,48,50,71)	2.41 (1.47 to 3.97)	15 (9.87 to 23)		
Ser. A - month 12 (N=43,44,45,45,50,71)	1.68 (0.99 to 2.85)	11 (6.65 to 17)		
Ser. C - month 1 (N=48,48,48,47,50,70)	1.42 (0.87 to 2.32)	16 (11 to 25)		
Ser. C - month 3 (N=49,47,46,46,50,70)	2.36 (1.54 to 3.59)	9.54 (6.61 to 14)		
Ser. C - month 6 (N=46,48,47,46,49,69)	1.07 (0.7 to 1.63)	5.14 (3.57 to 7.39)		
Ser. C - month 7 (N=48,47,46,47,50,71)	0.85 (0.55 to 1.3)	3.9 (2.7 to 5.64)		
Ser. C - month 12 (N=44,46,46,44,50,71)	0.99 (0.65 to 1.52)	3.06 (2.12 to 4.4)		
Ser. W - month 1 (N=48,47,47,46,49,72)	1.15 (0.68 to 1.95)	10 (6.49 to 16)		
Ser. W - month 3 (N=49,45,47,46,50,72)	4.83 (2.76 to 8.46)	7.32 (4.53 to 12)		
Ser. W - month 6 (N=44,46,45,43,43,69)	0.58 (0.33 to 1.02)	5.17 (3.25 to 8.24)		
Ser. W - month 7 (N=46,46,45,45,45,72)	0.55 (0.31 to 0.97)	5.47 (3.4 to 8.8)		
Ser. W - month 12 (N=45,44,45,42,46,69)	0.49 (0.27 to 0.89)	3.62 (2.21 to 5.94)		
Ser. Y - month 1 (N=48,47,48,49,49,73)	1.02 (0.66 to 1.58)	16 (11 to 23)		
Ser. Y - month 3 (N=49,47,47,49,50,73)	0.8 (0.56 to 1.15)	12 (8.54 to 16)		
Ser. Y - month 6 (N=48,47,48,48,49,72)	0.35 (0.21 to 0.56)	14 (9.04 to 21)		
Ser. Y - month 7 (N=46,47,46,49,50,72)	0.35 (0.21 to 0.56)	12 (7.76 to 18)		
Ser. Y - month 12 (N=45,46,45,46,50,70)	0.27 (0.16 to 0.45)	7.27 (4.68 to 11)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0 and Month 2 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMT Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0 and Month 2 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo ^[13]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers Against Serogroup B Test Strains after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, and 6, 7 and 12 months after the first vaccination with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 0, 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	2ABCWY	2ABx2CWY	2ABCWY+OMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	49	48	49
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 0 (N=49,48,47,48,50,73)	1.19 (0.93 to 1.53)	1.39 (1.08 to 1.79)	1.31 (1.01 to 1.69)	1.3 (1.01 to 1.68)
H44/76 (fHbp) - month 1 (N=48,48,48,49,50,73)	5.56 (3.44 to 8.99)	10 (6.38 to 17)	15 (9.5 to 25)	11 (6.93 to 18)
H44/76 (fHbp) - month 3 (N=49,48,46,48,50,72)	74 (53 to 102)	114 (82 to 158)	114 (81 to 159)	133 (96 to 186)
H44/76 (fHbp) - month 6 (N=47,48,48,48,50,72)	7.87 (5.04 to 12)	7.76 (4.98 to 12)	9.44 (6.04 to 15)	14 (9.2 to 23)
H44/76 (fHbp) - month 7 (N=48,48,47,49,49,73)	4.62 (3.04 to 7.02)	5.75 (3.79 to 8.73)	6.12 (4 to 9.37)	11 (7.15 to 17)
H44/76 (fHbp) - month 12 (N=45,47,45,46,50,71)	3.24 (2.18 to 4.8)	2.31 (1.57 to 3.39)	4 (2.69 to 5.97)	4.31 (2.91 to 6.4)
5/99 (NadA) - month 0 (N=49,49,48,48,50,73)	2.48 (1.81 to 3.39)	2.17 (1.59 to 2.96)	1.87 (1.36 to 2.56)	2.02 (1.47 to 2.78)
5/99 (NadA) - month 1 (N=48,48,47,49,50,72)	44 (29 to 65)	91 (62 to 135)	23 (15 to 34)	34 (23 to 51)
5/99 (NadA) - month 3 (N=49,48,47,47,50,71)	257 (203 to 324)	401 (318 to 507)	337 (266 to 427)	363 (285 to 462)
5/99 (NadA) - month 6 (N=47,49,48,48,48,72)	69 (51 to 93)	122 (91 to 163)	55 (41 to 74)	72 (53 to 97)
5/99 (NadA) - month 7 (N=47,48,47,49,50,73)	55 (42 to 73)	96 (72 to 127)	44 (33 to 58)	59 (45 to 79)
5/99 (NadA) - month 12 (N=45,47,46,46,50,72)	31 (22 to 44)	46 (33 to 64)	30 (21 to 42)	35 (25 to 49)
NZ98/254 (PorA) - month 0 (N=49,49,48,48,50,73)	1.76 (1.42 to 2.19)	1.62 (1.3 to 2.01)	1.77 (1.42 to 2.2)	1.76 (1.41 to 2.2)
NZ98/254 (PorA) - month 1 (N=48,48,48,49,50,72)	2.14 (1.58 to 2.9)	2.42 (1.8 to 3.26)	4.95 (3.66 to 6.7)	4.26 (3.15 to 5.77)
NZ98/254 (PorA) - month 3 (N=49,48,47,48,50,72)	2.98 (2.18 to 4.06)	3.86 (2.83 to 5.26)	14 (10 to 19)	12 (8.96 to 17)
NZ98/254 (PorA) - month 6 (N=48,49,48,48,49,72)	1.7 (1.28 to 2.26)	1.88 (1.42 to 2.48)	3.19 (2.4 to 4.25)	3.09 (2.31 to 4.13)
NZ98/254 (PorA) - month 7 (N=47,48,47,49,50,73)	1.45 (1.05 to 2)	1.76 (1.29 to 2.41)	2.62 (1.9 to 3.62)	2.49 (1.81 to 3.43)
NZ98/254 (PorA) - month 12 (N=45,47,46,46,50,72)	1.57 (1.2 to 2.06)	1.6 (1.23 to 2.09)	2.47 (1.89 to 3.24)	2.18 (1.66 to 2.86)
M14459 (fHBP) - month 0 (N=49,48,45,45,50,72)	1.29 (1.05 to 1.59)	1.43 (1.16 to 1.75)	1.43 (1.16 to 1.78)	1.38 (1.11 to 1.72)
M14459 (fHBP) - month 1 (N=48,48,47,49,50,72)	1.99 (1.44 to 2.75)	2.66 (1.92 to 3.68)	4.59 (3.28 to 6.44)	3.47 (2.47 to 4.89)
M14459 (fHBP) - month 3 (N=49,48,45,43,50,70)	6.31 (4.28 to 9.32)	13 (8.91 to 20)	17 (11 to 26)	20 (13 to 30)
M14459 (fHBP) - month 6 (N=47,47,48,48,50,71)	2.1 (1.59 to 2.79)	2.63 (1.99 to 3.49)	3.33 (2.49 to 4.44)	3.15 (2.35 to 4.24)
M14459 (fHBP) - month 7 (N=47,48,47,49,50,73)	1.79 (1.29 to 2.49)	2.4 (1.74 to 3.33)	2.75 (1.96 to 3.86)	3.59 (2.55 to 5.06)
M14459 (fHBP) - month 12 (N=45,47,45,47,50,72)	1.73 (1.31 to 2.27)	1.64 (1.25 to 2.14)	2.43 (1.83 to 3.23)	2.53 (1.91 to 3.36)

M07-0241084 (NHBA) - month 0 (N=48,46,37,44,50,67)	2.9 (1.97 to 4.27)	4.04 (2.74 to 5.97)	3.57 (2.3 to 5.56)	3.19 (2.13 to 4.78)
M07-0241084 (NHBA) - month 1 (N=48,48,48,48,50,72)	2.88 (2.17 to 3.81)	3.17 (2.39 to 4.21)	7.11 (5.18 to 9.76)	5.51 (4.12 to 7.36)
M07-0241084 (NHBA) - month 3 (N=48,48,42,45,49,68)	4.34 (3.27 to 5.75)	6.27 (4.71 to 8.33)	12 (8.71 to 17)	14 (10 to 19)
M07-0241084 (NHBA) - month 6 (N=47,48,48,48,49,70)	3.78 (2.88 to 4.95)	3.3 (2.51 to 4.34)	5.43 (4 to 7.37)	6.93 (5.23 to 9.19)
M07-0241084 (NHBA) - month 7 (N=47,48,47,48,50,72)	3.51 (2.54 to 4.85)	3.19 (2.3 to 4.41)	5.18 (3.58 to 7.48)	6.58 (4.7 to 9.22)
M07-0241084 (NHBA) - month 12 (N=45,46,45,47,50,70)	3.71 (2.74 to 5.03)	2.82 (2.08 to 3.83)	4.92 (3.51 to 6.89)	6.16 (4.53 to 8.38)
M01-0240364 (NadA) - month 0 (N=49,47,44,45,50,72)	1.15 (0.9 to 1.46)	1.37 (1.08 to 1.75)	1.25 (0.97 to 1.61)	1.45 (1.12 to 1.86)
M01-0240364 (NadA) - month 1 (N=48,44,46,48,50,72)	5.46 (3.1 to 9.61)	6.42 (3.54 to 12)	4.7 (2.58 to 8.58)	4.24 (2.33 to 7.71)
M01-0240364 (NadA) - month 3 (N=48,48,44,42,49,70)	67 (38 to 118)	192 (109 to 339)	133 (72 to 245)	125 (67 to 233)
M01-0240364 (NadA) - month 6 (N=46,48,48,48,48,71)	8.59 (4.95 to 15)	17 (9.65 to 29)	11 (6.48 to 20)	6.27 (3.52 to 11)
M01-0240364 (NadA) - month 7 (N=44,48,48,48,50,71)	5.38 (3.2 to 9.03)	9.65 (5.83 to 16)	7.51 (4.45 to 13)	4.13 (2.43 to 7.01)
M01-0240364 (NadA) - month 12 (N=43,45,44,44,50,72)	3.85 (2.16 to 6.84)	4.79 (2.72 to 8.44)	5.76 (3.19 to 10)	3.23 (1.78 to 5.87)

End point values	Men 2B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	73		
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 0 (N=49,48,47,48,50,73)	1.42 (1.1 to 1.82)	1.31 (1.05 to 1.65)		
H44/76 (fHbp) - month 1 (N=48,48,48,49,50,73)	4.56 (2.84 to 7.3)	1.51 (1.19 to 1.92)		
H44/76 (fHbp) - month 3 (N=49,48,46,48,50,72)	44 (32 to 61)	1.27 (1.07 to 1.5)		
H44/76 (fHbp) - month 6 (N=47,48,48,48,50,72)	4.34 (2.81 to 6.71)	1.18 (1.01 to 1.37)		
H44/76 (fHbp) - month 7 (N=48,48,47,49,49,73)	3.55 (2.35 to 5.37)	1.21 (1.04 to 1.4)		
H44/76 (fHbp) - month 12 (N=45,47,45,46,50,71)	2.42 (1.66 to 3.52)	1.13 (1 to 1.29)		
5/99 (NadA) - month 0 (N=49,49,48,48,50,73)	3.16 (2.32 to 4.32)	2.25 (1.77 to 2.85)		
5/99 (NadA) - month 1 (N=48,48,47,49,50,72)	58 (39 to 85)	2.27 (1.82 to 2.85)		
5/99 (NadA) - month 3 (N=49,48,47,47,50,71)	322 (255 to 406)	2.11 (1.65 to 2.7)		
5/99 (NadA) - month 6 (N=47,49,48,48,48,72)	73 (54 to 98)	1.74 (1.36 to 2.22)		
5/99 (NadA) - month 7 (N=47,48,47,49,50,73)	68 (51 to 90)	1.93 (1.5 to 2.48)		
5/99 (NadA) - month 12 (N=45,47,46,46,50,72)	32 (23 to 44)	1.53 (1.25 to 1.88)		
NZ98/254 (PorA) - month 0 (N=49,49,48,48,50,73)	2.37 (1.91 to 2.94)	1.5 (1.3 to 1.73)		

NZ98/254 (PorA) - month 1 (N=48,48,48,49,50,72)	2.01 (1.49 to 2.71)	1.51 (1.32 to 1.74)		
NZ98/254 (PorA) - month 3 (N=49,48,47,48,50,72)	2.81 (2.06 to 3.84)	1.49 (1.29 to 1.72)		
NZ98/254 (PorA) - month 6 (N=48,49,48,48,49,72)	1.47 (1.1 to 1.95)	1.15 (1.05 to 1.25)		
NZ98/254 (PorA) - month 7 (N=47,48,47,49,50,73)	1.45 (1.06 to 2)	1.2 (1.07 to 1.33)		
NZ98/254 (PorA) - month 12 (N=45,47,46,46,50,72)	1.21 (0.93 to 1.57)	1.15 (1.05 to 1.25)		
M14459 (fHBP) - month 0 (N=49,48,45,45,50,72)	1.89 (1.54 to 2.32)	1.33 (1.08 to 1.62)		
M14459 (fHBP) - month 1 (N=48,48,47,49,50,72)	2.02 (1.46 to 2.8)	1.26 (1.08 to 1.47)		
M14459 (fHBP) - month 3 (N=49,48,45,43,50,70)	5.04 (3.39 to 7.47)	1.29 (1.1 to 1.51)		
M14459 (fHBP) - month 6 (N=47,47,48,48,50,71)	2.05 (1.55 to 2.71)	1.28 (1.11 to 1.49)		
M14459 (fHBP) - month 7 (N=47,48,47,49,50,73)	1.87 (1.35 to 2.59)	1.28 (1.1 to 1.49)		
M14459 (fHBP) - month 12 (N=45,47,45,47,50,72)	1.44 (1.1 to 1.87)	1.37 (1.15 to 1.64)		
M07-0241084 (NHBA) - month 0 (N=48,46,37,44,50,67)	5.63 (3.85 to 8.22)	2.67 (1.88 to 3.79)		
M07-0241084 (NHBA) - month 1 (N=48,48,48,48,50,72)	3.76 (2.85 to 4.97)	2.68 (1.93 to 3.7)		
M07-0241084 (NHBA) - month 3 (N=48,48,42,45,49,68)	6.25 (4.71 to 8.28)	2.85 (2.08 to 3.91)		
M07-0241084 (NHBA) - month 6 (N=47,48,48,48,49,70)	3.36 (2.56 to 4.4)	2.99 (2.16 to 4.14)		
M07-0241084 (NHBA) - month 7 (N=47,48,47,48,50,72)	3.78 (2.74 to 5.2)	3.03 (2.22 to 4.15)		
M07-0241084 (NHBA) - month 12 (N=45,46,45,47,50,70)	3.09 (2.31 to 4.14)	2.91 (2.06 to 4.12)		
M01-0240364 (NadA) - month 0 (N=49,47,44,45,50,72)	1.47 (1.16 to 1.86)	1.12 (1.01 to 1.24)		
M01-0240364 (NadA) - month 1 (N=48,44,46,48,50,72)	4.25 (2.44 to 7.41)	1.12 (0.98 to 1.29)		
M01-0240364 (NadA) - month 3 (N=48,48,44,42,49,70)	88 (50 to 154)	1.41 (1.07 to 1.85)		
M01-0240364 (NadA) - month 6 (N=46,48,48,48,48,71)	7.02 (4.07 to 12)	1.18 (1 to 1.39)		
M01-0240364 (NadA) - month 7 (N=44,48,48,48,50,71)	5.72 (3.49 to 9.35)	1.18 (1 to 1.39)		
M01-0240364 (NadA) - month 12 (N=43,45,44,44,50,72)	2.88 (1.68 to 4.92)	1.15 (0.97 to 1.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMR Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0 and Month 2 With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMR Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0 and Month 2 With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo ^[14]
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End point description:

Antibody response was measured as Geometric Mean Ratios (95%CI) Against Serogroup B Test Strains after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, and after 6, 7 and 12 months of the first vaccination with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	2ABCWY	2ABx2CWY	2ABCWY+OMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	49	48	49
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 1 (N=48,47,47,48,50,73)	4.42 (2.73 to 7.16)	7.99 (4.95 to 13)	12 (7.44 to 20)	8.82 (5.43 to 14)
H44/76 (fHbp) - month 3 (N=49,47,45,47,50,72)	61 (42 to 87)	84 (58 to 121)	87 (60 to 127)	103 (71 to 150)
H44/76 (fHbp) - month 6 (N=47,47,47,47,50,72)	6.3 (4.01 to 9.9)	5.94 (3.79 to 9.3)	7.37 (4.69 to 12)	11 (7.14 to 18)
H44/76 (fHbp) - month 7 (N=48,47,46,48,49,73)	3.73 (2.43 to 5.75)	4.34 (2.82 to 6.68)	4.75 (3.06 to 7.37)	8.48 (5.49 to 13)
H44/76 (fHbp) - month 12 (N=45,46,44,45,50,71)	2.58 (1.73 to 3.84)	1.77 (1.2 to 2.61)	3.11 (2.08 to 4.66)	3.41 (2.29 to 5.09)
5/99 (NadA) - month 1 (N=48,48,47,48,50,72)	18 (12 to 29)	42 (27 to 65)	12 (7.41 to 18)	16 (10 to 26)
5/99 (NadA) - month 3 (N=49,48,47,46,50,71)	106 (74 to 151)	184 (129 to 263)	176 (122 to 253)	174 (120 to 252)
5/99 (NadA) - month 6 (N=47,49,48,47,48,72)	28 (19 to 41)	56 (39 to 82)	29 (20 to 42)	35 (24 to 51)
5/99 (NadA) - month 7 (N=47,48,47,48,50,73)	23 (16 to 34)	44 (30 to 63)	23 (16 to 33)	29 (20 to 42)
5/99 (NadA) - month 12 (N=45,47,46,46,50,72)	13 (8.78 to 20)	21 (14 to 31)	15 (10 to 23)	18 (12 to 28)
NZ98/254 (PorA) - month 1 (N=48,48,48,48,50,72)	1.27 (0.93 to 1.73)	1.46 (1.07 to 1.98)	2.91 (2.14 to 3.96)	2.51 (1.84 to 3.42)
NZ98/254 (PorA) - month 3 (N=49,48,47,47,50,72)	1.74 (1.26 to 2.4)	2.33 (1.69 to 3.21)	8.25 (5.95 to 11)	7.17 (5.16 to 9.96)
NZ98/254 (PorA) - month 6 (N=48,49,48,47,49,72)	0.99 (0.73 to 1.33)	1.14 (0.85 to 1.53)	1.86 (1.38 to 2.52)	1.79 (1.32 to 2.44)
NZ98/254 (PorA) - month 7 (N=47,48,47,48,50,73)	0.85 (0.61 to 1.19)	1.07 (0.76 to 1.49)	1.53 (1.09 to 2.15)	1.45 (1.03 to 2.03)
NZ98/254 (PorA) - month 12 (N=45,47,46,45,50,72)	0.91 (0.68 to 1.22)	0.97 (0.73 to 1.29)	1.41 (1.05 to 1.88)	1.25 (0.93 to 1.68)
M14459 (fHBP) - month 1 (N=48,47,44,45,50,71)	1.57 (1.13 to 2.17)	2.09 (1.51 to 2.89)	3.61 (2.58 to 5.06)	2.73 (1.95 to 3.84)
M14459 (fHBP) - month 3 (N=49,47,42,41,50,69)	4.96 (3.35 to 7.36)	10 (6.77 to 15)	13 (8.66 to 20)	15 (9.83 to 23)
M14459 (fHBP) - month 6 (N=47,46,45,44,50,70)	1.65 (1.25 to 2.19)	2.04 (1.54 to 2.71)	2.58 (1.94 to 3.45)	2.46 (1.83 to 3.31)
M14459 (fHBP) - month 7 (N=47,47,44,45,50,72)	1.4 (1 to 1.96)	1.82 (1.31 to 2.54)	2.08 (1.48 to 2.94)	2.75 (1.95 to 3.9)
M14459 (fHBP) - month 12 (n=45,46,42,43,50,71)	1.35 (1.02 to 1.77)	1.26 (0.96 to 1.65)	1.86 (1.4 to 2.47)	1.96 (1.48 to 2.61)

M07-0241084 (NHBA) - month 1 (N=47,45,37,44,50,66)	1.07 (0.81 to 1.42)	1.14 (0.86 to 1.52)	2.6 (1.89 to 3.57)	2.03 (1.52 to 2.73)
M07-0241084 (NHBA) - month 3 (N=47,45,33,40,49,65)	1.62 (1.19 to 2.19)	2.1 (1.55 to 2.85)	4.46 (3.11 to 6.39)	4.94 (3.56 to 6.84)
M07-0241084 (NHBA) - month 6 (N=46,45,37,43,49,65)	1.39 (1.04 to 1.85)	1.13 (0.85 to 1.5)	1.91 (1.39 to 2.64)	2.53 (1.88 to 3.4)
M07-0241084 (NHBA) - month 7 (N=46,45,36,43,50,66)	1.29 (0.91 to 1.82)	1.05 (0.74 to 1.48)	1.81 (1.22 to 2.68)	2.41 (1.68 to 3.46)
M07-0241084(NHBA) - month 12 (N=44,43,36,43,50,64)	1.38 (0.99 to 1.9)	0.94 (0.68 to 1.3)	1.7 (1.18 to 2.43)	2.24 (1.61 to 3.12)
M01-0240364 (NadA) - month 1 (N=48,42,42,44,50,71)	4.42 (2.51 to 7.77)	5.08 (2.8 to 9.2)	3.77 (2.07 to 6.88)	3.35 (1.84 to 6.08)
M01-0240364 (NadA) - month 3 (N=48,46,40,40,49,63)	57 (32 to 102)	145 (80 to 261)	105 (56 to 199)	89 (47 to 170)
M01-0240364 (NadA) - month 6 (N=46,46,44,44,48,70)	7.07 (4.05 to 12)	13 (7.46 to 22)	9.18 (5.17 to 16)	4.78 (2.68 to 8.54)
M01-0240364 (NadA) - month 7 (N=44,46,44,44,50,70)	4.46 (2.63 to 7.56)	7.43 (4.45 to 12)	6.03 (3.54 to 10)	3.11 (1.81 to 5.33)
M01-0240364 (NadA) - month12 (N=43,43,41,40,50,71)	3.17 (1.77 to 5.69)	3.77 (2.12 to 6.69)	4.65 (2.55 to 8.47)	2.52 (1.38 to 4.62)

End point values	Men 2B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	73		
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 1 (N=48,47,47,48,50,73)	3.53 (2.2 to 5.65)	1.15 (0.98 to 1.35)		
H44/76 (fHbp) - month 3 (N=49,47,45,47,50,72)	32 (22 to 46)	1.05 (0.89 to 1.24)		
H44/76 (fHbp) - month 6 (N=47,47,47,47,50,72)	3.31 (2.13 to 5.14)	0.89 (0.78 to 1.02)		
H44/76 (fHbp) - month 7 (N=48,47,46,48,49,73)	2.66 (1.73 to 4.08)	0.92 (0.79 to 1.06)		
H44/76 (fHbp) - month 12 (N=45,46,44,45,50,71)	1.85 (1.27 to 2.71)	0.86 (0.73 to 1.01)		
5/99 (NadA) - month 1 (N=48,48,47,48,50,72)	21 (13 to 33)	1 (0.85 to 1.18)		
5/99 (NadA) - month 3 (N=49,48,47,46,50,71)	107 (75 to 153)	1 (0.8 to 1.26)		
5/99 (NadA) - month 6 (N=47,49,48,47,48,72)	25 (17 to 37)	0.78 (0.61 to 0.99)		
5/99 (NadA) - month 7 (N=47,48,47,48,50,73)	23 (16 to 34)	0.86 (0.68 to 1.08)		
5/99 (NadA) - month 12 (N=45,47,46,46,50,72)	11 (7.48 to 16)	0.7 (0.59 to 0.83)		
NZ98/254 (PorA) - month 1 (N=48,48,48,48,50,72)	1.08 (0.8 to 1.46)	1 (0.87 to 1.16)		
NZ98/254 (PorA) - month 3 (N=49,48,47,47,50,72)	1.46 (1.06 to 2.01)	0.99 (0.83 to 1.17)		
NZ98/254 (PorA) - month 6 (N=48,49,48,47,49,72)	0.75 (0.56 to 1.02)	0.76 (0.65 to 0.89)		
NZ98/254 (PorA) - month 7 (N=47,48,47,48,50,73)	0.73 (0.52 to 1.01)	0.8 (0.67 to 0.94)		
NZ98/254 (PorA) - month 12 (N=45,47,46,45,50,72)	0.6 (0.46 to 0.8)	0.77 (0.66 to 0.9)		

M14459 (fHBP) - month 1 (N=48,47,44,45,50,71)	1.57 (1.14 to 2.16)	0.95 (0.87 to 1.03)		
M14459 (fHBP) - month 3 (N=49,47,42,41,50,69)	3.54 (2.4 to 5.23)	1.04 (0.9 to 1.2)		
M14459 (fHBP) - month 6 (N=47,46,45,44,50,70)	1.53 (1.16 to 2.02)	0.99 (0.87 to 1.12)		
M14459 (fHBP) - month 7 (N=47,47,44,45,50,72)	1.3 (0.94 to 1.8)	0.97 (0.83 to 1.13)		
M14459 (fHBP) - month 12 (n=45,46,42,43,50,71)	1.05 (0.81 to 1.37)	1.03 (0.87 to 1.24)		
M07-0241084 (NHBA) - month 1 (N=47,45,37,44,50,66)	1.31 (1 to 1.72)	1.02 (0.87 to 1.19)		
M07-0241084 (NHBA) - month 3 (N=47,45,33,40,49,65)	1.91 (1.42 to 2.56)	1.13 (0.89 to 1.44)		
M07-0241084 (NHBA) - month 6 (N=46,45,37,43,49,65)	1.07 (0.81 to 1.42)	1.2 (0.97 to 1.49)		
M07-0241084 (NHBA) - month 7 (N=46,45,36,43,50,66)	1.12 (0.8 to 1.57)	1.21 (0.96 to 1.51)		
M07-0241084(NHBA) - month 12 (N=44,43,36,43,50,64)	0.94 (0.69 to 1.28)	1.19 (0.9 to 1.58)		
M01-0240364 (NadA) - month 1 (N=48,42,42,44,50,71)	3.35 (1.93 to 5.83)	1 (0.86 to 1.16)		
M01-0240364 (NadA) - month 3 (N=48,46,40,40,49,63)	64 (36 to 113)	1.28 (1.01 to 1.63)		
M01-0240364 (NadA) - month 6 (N=46,46,44,44,48,70)	5.32 (3.08 to 9.19)	1.05 (0.9 to 1.23)		
M01-0240364 (NadA) - month 7 (N=44,46,44,44,50,70)	4.29 (2.6 to 7.08)	1.07 (0.92 to 1.25)		
M01-0240364 (NadA) - month12 (N=43,43,41,40,50,71)	2.17 (1.26 to 3.72)	1.03 (0.87 to 1.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT Against Serogroups A, C, W, and Y at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMT Against Serogroups A, C, W, and Y at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo ^[15]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers Against Serogroups A, C, W and Y at baseline (month 0), after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, after 6 month of the first vaccination (6 month) in the parent study and after the third vaccination (month 7) and 6 month after the third vaccination (month 12) with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 0, 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 0 (N=25,24,25,25,23,73)	1.34 (0.99 to 1.83)	1.5 (1.1 to 2.06)	1.19 (0.88 to 1.63)	1.47 (1.08 to 1.99)
Ser. A - month 1 (N=24,24,24,25,23,70)	42 (19 to 92)	98 (45 to 213)	44 (20 to 95)	46 (21 to 98)
Ser. A - month 3 (N=25,24,25,25,23,72)	132 (73 to 237)	252 (139 to 456)	185 (103 to 333)	153 (86 to 275)
Ser. A - month 6 (N=23,24,24,25,23,69)	14 (6.54 to 32)	40 (19 to 86)	32 (15 to 69)	19 (8.99 to 41)
Ser. A - month 7 (N=24,24,21,25,22,71)	247 (124 to 495)	296 (149 to 591)	253 (121 to 530)	256 (130 to 503)
Ser. A - month 12 (N=25,23,21,25,22,71)	33 (16 to 68)	58 (27 to 123)	47 (21 to 103)	38 (18 to 78)
Ser. C - month 0 (N=25,24,25,25,23,72)	6.67 (3.99 to 11)	4.9 (2.91 to 8.25)	4.75 (2.84 to 7.96)	6.3 (3.78 to 11)
Ser. C - month 1 (N=25,24,24,25,23,71)	125 (68 to 230)	87 (47 to 161)	112 (61 to 208)	74 (41 to 136)
Ser. C - month 3 (N=25,24,25,24,23,71)	482 (318 to 731)	384 (252 to 585)	346 (228 to 523)	381 (250 to 580)
Ser. C - month 6 (N=22,24,24,24,21,70)	182 (111 to 297)	143 (90 to 229)	157 (98 to 251)	118 (74 to 189)
Ser. C - month 7 (N=23,24,23,25,22,72)	676 (410 to 1114)	676 (416 to 1097)	636 (387 to 1046)	553 (344 to 891)
Ser. C - month 12 (N=25,23,21,25,23,72)	202 (123 to 334)	185 (110 to 309)	153 (89 to 263)	157 (96 to 258)
Ser. W - month 0 (N=25,24,25,25,23,73)	28 (13 to 59)	20 (9.17 to 42)	21 (9.83 to 44)	27 (13 to 56)
Ser. W - month 1 (N=25,24,24,25,23,72)	152 (92 to 253)	180 (108 to 300)	237 (141 to 396)	144 (87 to 238)
Ser. W - month 3 (N=25,24,25,24,23,72)	398 (285 to 557)	455 (324 to 639)	499 (357 to 697)	406 (289 to 570)
Ser. W - month 6 (N=24,24,25,24,22,69)	166 (105 to 261)	176 (112 to 275)	191 (123 to 297)	148 (94 to 231)
Ser. W - month 7 (N=23,24,21,25,21,72)	640 (405 to 1014)	670 (432 to 1039)	876 (548 to 1402)	627 (407 to 965)
Ser. W - month 12 (N=24,22,19,24,23,69)	264 (159 to 438)	258 (153 to 433)	257 (147 to 449)	212 (128 to 349)
Ser. Y - month 0 (N=25,24,25,25,23,73)	5.6 (3.58 to 8.74)	5.45 (3.47 to 8.57)	5.2 (3.33 to 8.13)	5.27 (3.38 to 8.2)
Ser. Y - month 1 (N=25,24,23,25,23,73)	75 (44 to 129)	48 (28 to 82)	62 (36 to 109)	71 (42 to 121)
Ser. Y - month 3 (N=25,24,25,25,23,73)	225 (154 to 328)	179 (122 to 262)	214 (147 to 312)	170 (117 to 247)
Ser. Y - month 6 (N=24,24,24,25,23,72)	185 (102 to 336)	216 (119 to 390)	147 (81 to 267)	121 (68 to 216)
Ser. Y - month 7 (N=25,24,24,25,22,72)	648 (362 to 1162)	590 (327 to 1066)	599 (331 to 1085)	408 (229 to 728)
Ser. Y - month 12 (N=25,23,21,25,23,70)	295 (158 to 550)	351 (184 to 670)	210 (107 to 413)	205 (110 to 381)

End point values	Men 3B	1ACWY		
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Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Titers				
geometric mean (confidence interval 95%)				
Ser. A - month 0 (N=25,24,25,25,23,73)	1.21 (0.88 to 1.67)	1.43 (1.18 to 1.72)		
Ser. A - month 1 (N=24,24,24,25,23,70)	4.35 (1.97 to 9.6)	107 (66 to 172)		
Ser. A - month 3 (N=25,24,25,25,23,72)	98 (53 to 181)	36 (25 to 52)		
Ser. A - month 6 (N=23,24,24,25,23,69)	4.65 (2.12 to 10)	20 (12 to 32)		
Ser. A - month 7 (N=24,24,21,25,22,71)	140 (68 to 289)	21 (13 to 31)		
Ser. A - month 12 (N=25,23,21,25,22,71)	11 (5.1 to 24)	14 (9.03 to 22)		
Ser. C - month 0 (N=25,24,25,25,23,72)	3.82 (2.24 to 6.52)	4.96 (3.61 to 6.81)		
Ser. C - month 1 (N=25,24,24,25,23,71)	5.93 (3.16 to 11)	75 (51 to 109)		
Ser. C - month 3 (N=25,24,25,24,23,71)	20 (13 to 31)	45 (35 to 58)		
Ser. C - month 6 (N=22,24,24,24,21,70)	4.58 (2.77 to 7.57)	23 (17 to 31)		
Ser. C - month 7 (N=23,24,23,25,22,72)	33 (20 to 55)	18 (13 to 24)		
Ser. C - month 12 (N=25,23,21,25,23,72)	7.8 (4.65 to 13)	14 (10 to 19)		
Ser. W - month 0 (N=25,24,25,25,23,73)	27 (12 to 58)	24 (15 to 38)		
Ser. W - month 1 (N=25,24,24,25,23,72)	19 (11 to 32)	210 (154 to 287)		
Ser. W - month 3 (N=25,24,25,24,23,72)	139 (98 to 197)	166 (135 to 204)		
Ser. W - month 6 (N=24,24,25,24,22,69)	10 (6.28 to 16)	117 (88 to 154)		
Ser. W - month 7 (N=23,24,21,25,21,72)	116 (72 to 187)	121 (93 to 159)		
Ser. W - month 12 (N=24,22,19,24,23,69)	17 (10 to 29)	75 (55 to 103)		
Ser. Y - month 0 (N=25,24,25,25,23,73)	4.4 (2.77 to 6.99)	7.07 (5.38 to 9.29)		
Ser. Y - month 1 (N=25,24,23,25,23,73)	4.38 (2.51 to 7.67)	92 (66 to 128)		
Ser. Y - month 3 (N=25,24,25,25,23,73)	4.91 (3.32 to 7.26)	72 (57 to 91)		
Ser. Y - month 6 (N=24,24,24,25,23,72)	1.69 (0.92 to 3.09)	84 (58 to 120)		
Ser. Y - month 7 (N=25,24,24,25,22,72)	2.56 (1.38 to 4.77)	75 (52 to 108)		
Ser. Y - month 12 (N=25,23,21,25,23,70)	1.46 (0.76 to 2.78)	47 (31 to 69)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMR Against Serogroups A, C, W, and Y at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMR Against Serogroups A, C, W, and Y at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo ^[16]
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End point description:

Antibody response was measured as Geometric Mean Ratios (95%CI) Against Serogroup B Test Strains after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, after 6 month of the first vaccination (6 month) in the parent study and after the third vaccination (month 7) and 6 month after the third vaccination (month 12) with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A - month 1 (N=24,24,24,25,23,70)	32 (15 to 71)	71 (32 to 155)	35 (16 to 77)	33 (15 to 72)
Ser. A - month 3 (N=25,24,25,25,23,72)	99 (53 to 185)	176 (94 to 330)	150 (81 to 280)	109 (59 to 202)
Ser. A - month 6 (N=23,24,24,25,23,69)	11 (4.86 to 24)	29 (13 to 63)	25 (12 to 56)	14 (6.47 to 30)
Ser. A - month 7 (N=24,24,21,25,22,71)	190 (94 to 385)	214 (106 to 432)	201 (95 to 425)	187 (94 to 372)
Ser. A - month 12 (N=25,23,21,25,22,71)	25 (12 to 52)	42 (20 to 90)	36 (16 to 81)	28 (13 to 57)
Ser. C - month 1 (N=25,24,24,25,23,70)	23 (11 to 45)	19 (9.55 to 38)	26 (13 to 52)	14 (7.09 to 28)
Ser. C - month 3 (N=25,24,25,24,23,70)	80 (44 to 143)	81 (45 to 148)	75 (42 to 135)	63 (35 to 114)
Ser. C - month 6 (N=22,24,24,24,21,69)	33 (18 to 61)	31 (17 to 56)	33 (19 to 60)	22 (12 to 39)
Ser. C - month 7 (N=23,24,23,25,22,71)	115 (62 to 214)	146 (80 to 266)	139 (75 to 258)	100 (56 to 181)
Ser. C - month 12 (N=25,23,21,25,23,71)	37 (21 to 67)	41 (22 to 75)	33 (18 to 63)	30 (17 to 53)
Ser. W - month 1 (N=25,24,24,25,23,72)	6.44 (3.12 to 13)	9.65 (4.64 to 20)	13 (6.09 to 27)	6.3 (3.07 to 13)
Ser. W - month 3 (N=25,24,25,24,23,72)	15 (6.85 to 33)	24 (11 to 52)	24 (11 to 53)	14 (6.51 to 31)
Ser. W - month 6 (N=24,24,25,24,22,69)	6.45 (3.03 to 14)	9.27 (4.4 to 20)	9.6 (4.6 to 20)	6.36 (3.02 to 13)
Ser. W - month 7 (N=23,24,21,25,21,72)	24 (11 to 54)	35 (16 to 76)	41 (18 to 94)	26 (12 to 55)
Ser. W - month 12 (N=24,22,19,24,23,69)	11 (4.99 to 24)	15 (6.76 to 34)	15 (6.38 to 37)	9.44 (4.32 to 21)
Ser. Y - month 1 (N=25,24,23,25,23,73)	15 (8.32 to 28)	9.78 (5.33 to 18)	13 (6.88 to 24)	15 (8.2 to 27)

Ser. Y - month 3 (N=25,24,25,25,23,73)	43 (26 to 71)	35 (21 to 58)	43 (26 to 72)	34 (21 to 56)
Ser. Y - month 6 (N=24,24,24,25,23,72)	36 (18 to 70)	43 (22 to 84)	30 (15 to 59)	25 (13 to 48)
Ser. Y - month 7 (N=25,24,24,25,22,72)	123 (63 to 242)	115 (58 to 227)	129 (65 to 257)	81 (42 to 159)
Ser. Y - month 12 (N=25,23,21,25,23,70)	56 (28 to 114)	67 (32 to 139)	43 (20 to 93)	41 (20 to 83)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Ratio				
geometric mean (confidence interval 95%)				
Ser. A - month 1 (N=24,24,24,25,23,70)	3.45 (1.54 to 7.73)	78 (48 to 127)		
Ser. A - month 3 (N=25,24,25,25,23,72)	79 (42 to 150)	26 (18 to 38)		
Ser. A - month 6 (N=23,24,24,25,23,69)	3.69 (1.66 to 8.2)	15 (9.12 to 24)		
Ser. A - month 7 (N=24,24,21,25,22,71)	110 (53 to 230)	15 (9.87 to 23)		
Ser. A - month 12 (N=25,23,21,25,22,71)	8.75 (4.01 to 19)	11 (6.65 to 17)		
Ser. C - month 1 (N=25,24,24,25,23,70)	1.51 (0.74 to 3.07)	16 (11 to 25)		
Ser. C - month 3 (N=25,24,25,24,23,70)	5.17 (2.81 to 9.52)	9.54 (6.61 to 14)		
Ser. C - month 6 (N=22,24,24,24,21,69)	1.16 (0.62 to 2.18)	5.14 (3.57 to 7.39)		
Ser. C - month 7 (N=23,24,23,25,22,71)	9.09 (4.84 to 17)	3.9 (2.7 to 5.64)		
Ser. C - month 12 (N=25,23,21,25,23,71)	2.01 (1.09 to 3.69)	3.06 (2.12 to 4.4)		
Ser. W - month 1 (N=25,24,24,25,23,72)	0.81 (0.38 to 1.72)	10 (6.49 to 16)		
Ser. W - month 3 (N=25,24,25,24,23,72)	5.42 (2.42 to 12)	7.32 (4.53 to 12)		
Ser. W - month 6 (N=24,24,25,24,22,69)	0.45 (0.21 to 0.98)	5.17 (3.25 to 8.24)		
Ser. W - month 7 (N=23,24,21,25,21,72)	4.78 (2.08 to 11)	5.47 (3.4 to 8.8)		
Ser. W - month 12 (N=24,22,19,24,23,69)	0.75 (0.34 to 1.67)	3.62 (2.21 to 5.94)		
Ser. Y - month 1 (N=25,24,23,25,23,73)	1.02 (0.55 to 1.9)	16 (11 to 23)		
Ser. Y - month 3 (N=25,24,25,25,23,73)	1.13 (0.67 to 1.9)	12 (8.54 to 16)		
Ser. Y - month 6 (N=24,24,24,25,23,72)	0.39 (0.2 to 0.78)	14 (9.04 to 21)		
Ser. Y - month 7 (N=25,24,24,25,22,72)	0.55 (0.27 to 1.14)	12 (7.76 to 18)		
Ser. Y - month 12 (N=25,23,21,25,23,70)	0.33 (0.16 to 0.69)	7.27 (4.68 to 11)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMT against N Meningitidis Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMT against N Meningitidis Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at 0, 2 and 6 Months With One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo ^[17]
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End point description:

Antibody response was measured as Geometric Mean hSBA Titers Against Serogroup B Test Strains at baseline (month 0), after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, after 6 month of the first vaccination (6 month) in the parent study and after the third vaccination (month 7) and 6 month after the third vaccination (month 12) with One of Four MenACWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 0, 1, 3, 6, 7 and 12

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 0 (N=25,24,25,25,23,73)	1.32 (0.93 to 1.87)	1.36 (0.96 to 1.93)	1.43 (1.01 to 2.02)	1.2 (0.85 to 1.7)
H44/76 (fHbp) - month 1 (N=25,24,24,24,23,73)	4.84 (2.52 to 9.3)	14 (7 to 26)	22 (11 to 42)	11 (5.83 to 22)
H44/76 (fHbp) - month 3 (N=25,24,24,25,23,72)	62 (40 to 97)	115 (73 to 180)	153 (97 to 241)	110 (71 to 171)
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	5.75 (3.15 to 11)	6.56 (3.56 to 12)	11 (5.95 to 20)	5.41 (2.93 to 9.98)
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	108 (61 to 190)	149 (84 to 264)	169 (95 to 302)	118 (67 to 208)
H44/76 (fHbp) - month 12 (N=25,23,21,25,23,71)	5.42 (3.22 to 9.11)	9.63 (5.64 to 16)	22 (12 to 38)	8.09 (4.84 to 14)
5/99 (NadA) - month 0 (N=25,24,25,25,23,73)	2.48 (1.61 to 3.82)	2.16 (1.4 to 3.34)	2 (1.3 to 3.07)	2.17 (1.42 to 3.33)
5/99 (NadA) - month 1 (N=25,24,24,25,23,72)	54 (31 to 93)	128 (74 to 222)	29 (17 to 51)	42 (24 to 71)
5/99 (NadA) - month 3 (N=24,24,25,24,23,71)	328 (237 to 455)	426 (308 to 589)	367 (267 to 506)	382 (277 to 528)

5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	75 (50 to 112)	122 (81 to 183)	48 (32 to 72)	84 (56 to 125)
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	530 (361 to 779)	741 (502 to 1092)	674 (456 to 996)	527 (360 to 771)
5/99 (NadA) - month 12 (N=25,23,21,25,23,72)	140 (89 to 220)	202 (127 to 322)	126 (77 to 206)	127 (81 to 199)
NZ98/254 (PorA) - month 0 (N=25,24,25,25,23,73)	1.78 (1.32 to 2.4)	1.69 (1.25 to 2.29)	1.77 (1.32 to 2.39)	1.78 (1.33 to 2.4)
NZ98/254 (PorA) - month 1 (N=25,24,24,25,23,72)	2.13 (1.41 to 3.21)	2.22 (1.46 to 3.36)	6.22 (4.09 to 9.45)	2.92 (1.95 to 4.39)
NZ98/254 (PorA) - month 3 (N=25,24,25,24,23,72)	2.87 (1.87 to 4.4)	3.14 (2.04 to 4.83)	18 (12 to 27)	8.95 (5.82 to 14)
NZ98/254 (PorA) - month 6 (N=25,24,24,25,23,72)	1.9 (1.29 to 2.81)	1.85 (1.25 to 2.74)	3.33 (2.24 to 4.96)	1.83 (1.24 to 2.69)
NZ98/254 (PorA) - month 7 (N=25,24,24,25,23,73)	2.3 (1.49 to 3.54)	3.24 (2.09 to 5.02)	23 (15 to 35)	12 (7.5 to 18)
NZ98/254 (PorA) - month 12 (N=25,23,21,25,23,72)	1.41 (0.98 to 2.02)	1.94 (1.34 to 2.81)	5.01 (3.4 to 7.39)	2.39 (1.68 to 3.42)
M14459 (fHBP) - month 0 (N=25,24,25,22,23,72)	1.57 (1.19 to 2.09)	1.64 (1.23 to 2.18)	1.45 (1.09 to 1.93)	1.32 (0.98 to 1.78)
M14459 (fHBP) - month 1 (N=25,24,24,25,23,72)	1.87 (1.2 to 2.91)	2.78 (1.78 to 4.36)	4.4 (2.8 to 6.91)	2.69 (1.69 to 4.29)
M14459 (fHBP) - month 3 (N=25,24,25,24,23,70)	5.94 (3.47 to 10)	15 (8.59 to 25)	22 (13 to 38)	11 (6.03 to 19)
M14459 (fHBP) - month 6 (N=25,24,25,25,23,71)	2.25 (1.54 to 3.3)	2.64 (1.8 to 3.89)	4 (2.73 to 5.86)	2.11 (1.42 to 3.15)
M14459 (fHBP) - month 7 (N=25,24,23,25,22,73)	14 (9.12 to 22)	23 (14 to 36)	41 (26 to 65)	17 (11 to 27)
M14459 (fHBP) - month 12 (N=25,23,21,25,23,72)	1.79 (1.25 to 2.57)	2.663 (1.81 to 3.81)	5.99 (4.06 to 8.85)	2.35 (1.61 to 3.43)
M07-0241084(NHBA) - month 0 (N=24,23,23,21,23,67)	2.79 (1.64 to 4.76)	3.33 (1.94 to 5.72)	3.24 (1.88 to 5.58)	3.46 (1.95 to 6.12)
M07-0241084(NHBA) - month 1 (N=25,24,23,23,23,72)	3.42 (2.33 to 5.02)	3.23 (2.19 to 4.75)	6.8 (4.57 to 10)	5.73 (3.76 to 8.71)
M07-0241084 (NHBA) - month 3 (N=25,24,22,21,22,68)	4.04 (2.75 to 5.93)	5.1 (3.46 to 7.53)	12 (8.04 to 19)	8.09 (5.18 to 13)
M07-0241084 (NHBA) - month 6 (N=25,23,23,25,23,70)	3.27 (2.26 to 4.73)	3.21 (2.19 to 4.69)	5.91 (3.99 to 8.74)	4.57 (3.08 to 6.78)
M07-0241084 (NHBA) - month 7 (N=25,23,22,25,21,72)	12 (7.85 to 19)	8.91 (5.64 to 14)	33 (20 to 53)	22 (14 to 35)
M07-0241084(NHBA) - month 12 (N=25,23,21,25,23,70)	2.77 (1.85 to 4.13)	3.05 (2.01 to 4.61)	9.99 (6.39 to 16)	4.92 (3.2 to 7.56)
M01-0240364 (NadA) - month 0 (N=25,24,24,22,23,72)	1.37 (0.99 to 1.91)	1.32 (0.95 to 1.84)	1.18 (0.84 to 1.65)	1.11 (0.79 to 1.57)
M01-0240364 (NadA) - month 1 (N=23,24,24,25,23,72)	2.94 (1.32 to 6.58)	10 (4.75 to 22)	6 (2.71 to 13)	5.52 (2.46 to 12)
M01-0240364 (NadA) - month 3 (N=25,24,24,24,23,70)	41 (19 to 88)	245 (113 to 532)	126 (57 to 280)	205 (91 to 459)
M01-0240364 (NadA) - month 6 (N=25,21,24,24,21,71)	4.39 (2.09 to 9.19)	9.54 (4.3 to 21)	7.3 (3.44 to 15)	9.08 (4.1 to 20)
M01-0240364 (NadA) - month 7 (N=24,23,24,25,23,71)	294 (147 to 589)	513 (255 to 1035)	409 (202 to 829)	280 (137 to 572)
M01-0240364(NadA) - month 12 (N=23,21,20,25,22,72)	7.32 (3.4 to 16)	24 (11 to 54)	17 (7.37 to 38)	19 (8.71 to 41)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		

Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 0 (N=25,24,25,25,23,73)	1.37 (0.96 to 1.96)	1.31 (1.05 to 1.65)		
H44/76 (fHbp) - month 1 (N=25,24,24,24,23,73)	5.03 (2.55 to 9.9)	1.51 (1.19 to 1.92)		
H44/76 (fHbp) - month 3 (N=25,24,24,25,23,72)	71 (45 to 112)	1.27 (1.07 to 1.5)		
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	6.1 (3.27 to 11)	1.18 (1.01 to 1.37)		
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	104 (57 to 191)	1.21 (1.04 to 1.4)		
H44/76 (fHbp) - month 12 (N=25,23,21,25,23,71)	9.02 (5.26 to 15)	1.13 (1 to 1.29)		
5/99 (NadA) - month 0 (N=25,24,25,25,23,73)	1.92 (1.23 to 3)	2.25 (1.77 to 2.85)		
5/99 (NadA) - month 1 (N=25,24,24,25,23,72)	157 (90 to 276)	2.27 (1.82 to 2.85)		
5/99 (NadA) - month 3 (N=24,24,25,24,23,71)	454 (326 to 632)	2.11 (1.65 to 2.7)		
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	156 (103 to 237)	1.74 (1.36 to 2.22)		
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	856 (575 to 1274)	1.93 (1.5 to 2.48)		
5/99 (NadA) - month 12 (N=25,23,21,25,23,72)	274 (172 to 439)	1.53 (1.25 to 1.88)		
NZ98/254 (PorA) - month 0 (N=25,24,25,25,23,73)	1.66 (1.22 to 2.27)	1.5 (1.3 to 1.73)		
NZ98/254 (PorA) - month 1 (N=25,24,24,25,23,72)	1.76 (1.15 to 2.7)	1.51 (1.32 to 1.74)		
NZ98/254 (PorA) - month 3 (N=25,24,25,24,23,72)	2.75 (1.77 to 4.28)	1.49 (1.29 to 1.72)		
NZ98/254 (PorA) - month 6 (N=25,24,24,25,23,72)	1.83 (1.22 to 2.73)	1.15 (1.05 to 1.25)		
NZ98/254 (PorA) - month 7 (N=25,24,24,25,23,73)	2.65 (1.69 to 4.14)	1.2 (1.07 to 1.33)		
NZ98/254 (PorA) - month 12 (N=25,23,21,25,23,72)	1.79 (1.23 to 2.59)	1.15 (1.05 to 1.25)		
M14459 (fHBP) - month 0 (N=25,24,25,22,23,72)	1.41 (1.05 to 1.9)	1.33 (1.08 to 1.62)		
M14459 (fHBP) - month 1 (N=25,24,24,25,23,72)	2.08 (1.32 to 3.3)	1.26 (1.08 to 1.47)		
M14459 (fHBP) - month 3 (N=25,24,25,24,23,70)	9.66 (5.55 to 17)	1.29 (1.1 to 1.51)		
M14459 (fHBP) - month 6 (N=25,24,25,25,23,71)	2.27 (1.53 to 3.37)	1.28 (1.11 to 1.49)		
M14459 (fHBP) - month 7 (N=25,24,23,25,22,73)	11 (6.77 to 17)	1.28 (1.1 to 1.49)		
M14459 (fHBP) - month 12 (N=25,23,21,25,23,72)	2.8 (1.93 to 4.07)	1.37 (1.15 to 1.64)		
M07-0241084(NHBA) - month 0 (N=24,23,23,21,23,67)	2.42 (1.41 to 4.16)	2.67 (1.88 to 3.79)		
M07-0241084(NHBA) - month 1 (N=25,24,23,23,23,72)	4.07 (2.76 to 6.01)	2.68 (1.93 to 3.7)		
M07-0241084 (NHBA) - month 3 (N=25,24,22,21,22,68)	6.48 (4.35 to 9.66)	2.85 (2.08 to 3.91)		
M07-0241084 (NHBA) - month 6 (N=25,23,23,25,23,70)	3.67 (2.52 to 5.34)	2.99 (2.16 to 4.14)		
M07-0241084 (NHBA) - month 7 (N=25,23,22,25,21,72)	11 (6.65 to 17)	3.03 (2.22 to 4.15)		

M07-0241084(NHBA) - month 12 (N=25,23,21,25,23,70)	5.74 (3.82 to 8.64)	2.91 (2.06 to 4.12)		
M01-0240364 (NadA) - month 0 (N=25,24,24,22,23,72)	1.11 (0.79 to 1.56)	1.12 (1.01 to 1.24)		
M01-0240364 (NadA) - month 1 (N=23,24,24,25,23,72)	3.84 (1.74 to 8.52)	1.12 (0.98 to 1.29)		
M01-0240364 (NadA) - month 3 (N=25,24,24,24,23,70)	226 (102 to 501)	1.41 (1.07 to 1.85)		
M01-0240364 (NadA) - month 6 (N=25,21,24,24,21,71)	7.87 (3.54 to 18)	1.18 (1 to 1.39)		
M01-0240364 (NadA) - month 7 (N=24,23,24,25,23,71)	507 (251 to 1027)	1.18 (1 to 1.39)		
M01-0240364(NadA) - month 12 (N=23,21,20,25,22,72)	41 (19 to 88)	1.15 (0.97 to 1.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: GMR Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0, 2 and 6 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo

End point title	GMR Against Serogroup B Test Strains at Month 0 Through Month 12 Following Vaccination at Month 0, 2 and 6 With One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo ^[18]
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End point description:

Antibody response was measured as Geometric Mean Ratios (95%CI) Against Serogroup B Test Strains after first (month 1) and second (month 3) vaccination during the parent study NCT01210885, after 6 month of the first vaccination (6 month) in the parent study and after the third vaccination (month 7) and 6 month after the third vaccination (month 12) with One of Four MenABCWY Formulations, rMenB, or MenACWY/Placebo.

End point type	Secondary
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End point timeframe:

At month 6 and month 7

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: No statistical analyses for this end point.

End point values	3ABCWY	3ABx2CWY	3ABCWY+OMV	3ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	25	25
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 1 (N=25,24,24,24,23,73)	3.79 (1.97 to 7.29)	11 (5.45 to 20)	17 (8.59 to 33)	8.95 (4.62 to 17)
H44/76 (fHbp) - month 3 (N=25,24,24,25,23,72)	48 (29 to 78)	86 (52 to 143)	111 (67 to 185)	90 (55 to 147)
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	4.47 (2.43 to 8.23)	5.06 (2.73 to 9.37)	8.28 (4.5 to 15)	4.31 (2.32 to 8.01)
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	83 (46 to 150)	113 (63 to 206)	126 (69 to 229)	95 (53 to 170)

H44/76 (fHbp) - month 12 (N=25,23,21,25,23,71)	4.22 (2.49 to 7.14)	7.44 (4.33 to 13)	16 (9.28 to 29)	6.45 (3.83 to 11)
5/99 (NadA) - month 1 (N=25,24,24,25,23,72)	23 (12 to 42)	60 (32 to 110)	14 (7.59 to 26)	19 (11 to 35)
5/99 (NadA) - month 3 (N=24,24,25,24,23,71)	131 (79 to 216)	197 (120 to 324)	182 (112 to 298)	182 (111 to 299)
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	31 (19 to 53)	56 (34 to 95)	24 (14 to 41)	39 (23 to 64)
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	221 (133 to 368)	344 (206 to 574)	325 (194 to 545)	244 (147 to 403)
5/99 (NadA) - month 12 (N=25,23,21,25,23,72)	58 (34 to 101)	95 (54 to 167)	62 (34 to 111)	58 (34 to 100)
NZ98/254 (PorA) - month 1 (N=25,24,24,25,23,72)	1.25 (0.82 to 1.9)	1.32 (0.86 to 2.02)	3.63 (2.37 to 5.57)	1.71 (1.13 to 2.6)
NZ98/254 (PorA) - month 3 (N=25,24,25,24,23,72)	1.67 (1.07 to 2.6)	1.86 (1.19 to 2.91)	10 (6.67 to 16)	5.16 (3.31 to 8.06)
NZ98/254 (PorA) - month 6 (N=25,24,24,25,23,72)	1.11 (0.73 to 1.67)	1.1 (0.73 to 1.67)	1.93 (1.27 to 2.92)	1.06 (0.71 to 1.59)
NZ98/254 (PorA) - month 7 (N=25,24,24,25,23,73)	1.33 (0.84 to 2.1)	1.93 (1.21 to 3.07)	13 (8.14 to 21)	6.66 (4.23 to 10)
NZ98/254 (PorA) - month 12 (N=25,23,21,25,23,72)	0.81 (0.55 to 1.19)	1.13 (0.76 to 1.69)	2.81 (1.85 to 4.27)	1.37 (0.94 to 2.02)
M14459 (fHBP) - month 1 (N=25,24,24,22,23,71)	1.46 (0.94 to 2.27)	2.18 (1.39 to 3.4)	3.46 (2.2 to 5.42)	2.12 (1.33 to 3.38)
M14459 (fHBP) - month 3 (N=25,24,25,22,23,69)	4.41 (2.57 to 7.57)	11 (6.28 to 19)	17 (9.77 to 29)	8.26 (4.68 to 15)
M14459 (fHBP) - month 6 (N=25,24,25,22,23,70)	1.73 (1.18 to 2.53)	2.02 (1.37 to 2.96)	3.1 (2.12 to 4.54)	1.66 (1.11 to 2.48)
M14459 (fHBP) - month 7 (N=25,24,23,22,22,72)	10 (6.66 to 16)	16 (10 to 26)	31 (19 to 49)	13 (8.26 to 21)
M14459 (fHBP) - month 12 (N=25,23,21,22,23,71)	1.35 (0.94 to 1.94)	1.97 (1.35 to 2.86)	4.57 (3.09 to 6.77)	1.83 (1.25 to 2.68)
M07-0241084 (NHBA) - month 1 (N=24,23,22,20,23,66)	1.28 (0.87 to 1.89)	1.19 (0.8 to 1.75)	2.5 (1.67 to 3.74)	2.1 (1.38 to 3.21)
M07-0241084 (NHBA) - month 3 (N=24,23,20,18,22,65)	1.52 (1 to 2.3)	1.82 (1.2 to 2.77)	4.54 (2.89 to 7.11)	2.81 (1.74 to 4.54)
M07-0241084 (NHBA) - month 6 (N=24,22,21,21,23,65)	1.22 (0.83 to 1.8)	1.14 (0.76 to 1.7)	2.14 (1.42 to 3.23)	1.62 (1.07 to 2.46)
M07-0241084 (NHBA) - month 7 (N=24,22,20,21,21,66)	4.55 (2.84 to 7.29)	3.1 (1.9 to 5.05)	12 (6.98 to 20)	7.7 (4.65 to 13)
M07-0241084 (NHBA) - month 12 (N=24,22,19,21,23,64)	1.03 (0.67 to 1.59)	1.07 (0.68 to 1.66)	3.56 (2.21 to 5.75)	1.73 (1.09 to 2.74)
M01-0240364 (NadA) - month 1 (N=23,24,23,22,23,71)	2.33 (1.04 to 5.2)	8.23 (3.79 to 18)	4.84 (2.19 to 11)	4.48 (2 to 10)
M01-0240364 (NadA) - month 3 (N=25,24,23,22,23,69)	31 (14 to 68)	190 (85 to 424)	105 (46 to 239)	177 (77 to 408)
M01-0240364 (NadA) - month 6 (N=25,21,24,21,21,70)	3.41 (1.62 to 7.2)	7.46 (3.33 to 17)	5.97 (2.79 to 13)	7.56 (3.39 to 17)
M01-0240364 (NadA) - month 7 (N=24,23,23,22,23,70)	226 (111 to 459)	401 (196 to 820)	336 (164 to 690)	236 (114 to 488)
M01-0240364 (NadA) - month 12 (N=23,21,20,22,22,71)	5.61 (2.58 to 12)	19 (8.45 to 42)	14 (6.13 to 32)	16 (7.28 to 35)

End point values	Men 3B	1ACWY		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	73		
Units: Ratio				

geometric mean (confidence interval 95%)				
H44/76 (fHbp) - month 1 (N=25,24,24,24,23,73)	3.92 (1.99 to 7.72)	1.15 (0.98 to 1.35)		
H44/76 (fHbp) - month 3 (N=25,24,24,25,23,72)	53 (32 to 89)	1.05 (0.89 to 1.24)		
H44/76 (fHbp) - month 6 (N=25,24,25,24,23,72)	4.7 (2.5 to 8.85)	0.89 (0.78 to 1.02)		
H44/76 (fHbp) - month 7 (N=25,24,24,25,22,73)	79 (42 to 147)	0.92 (0.79 to 1.06)		
H44/76 (fHbp) - month 12 (N=25,23,21,25,23,71)	6.97 (4.04 to 12)	0.86 (0.73 to 1.01)		
5/99 (NadA) - month 1 (N=25,24,24,25,23,72)	79 (42 to 148)	1 (0.85 to 1.18)		
5/99 (NadA) - month 3 (N=24,24,25,24,23,71)	233 (140 to 387)	1 (0.8 to 1.26)		
5/99 (NadA) - month 6 (N=25,24,24,25,23,72)	79 (46 to 134)	0.78 (0.61 to 0.99)		
5/99 (NadA) - month 7 (N=25,24,24,25,23,73)	435 (257 to 736)	0.86 (0.68 to 1.08)		
5/99 (NadA) - month 12 (N=25,23,21,25,23,72)	138 (78 to 243)	0.7 (0.59 to 0.83)		
NZ98/254 (PorA) - month 1 (N=25,24,24,25,23,72)	1.06 (0.68 to 1.63)	1 (0.87 to 1.16)		
NZ98/254 (PorA) - month 3 (N=25,24,25,24,23,72)	1.64 (1.04 to 2.6)	0.99 (0.83 to 1.17)		
NZ98/254 (PorA) - month 6 (N=25,24,24,25,23,72)	1.09 (0.71 to 1.67)	0.76 (0.65 to 0.89)		
NZ98/254 (PorA) - month 7 (N=25,24,24,25,23,73)	1.59 (0.99 to 2.55)	0.8 (0.67 to 0.94)		
NZ98/254 (PorA) - month 12 (N=25,23,21,25,23,72)	1.06 (0.71 to 1.58)	0.77 (0.66 to 0.9)		
M14459 (fHBP) - month 1 (N=25,24,24,22,23,71)	1.64 (1.04 to 2.59)	0.95 (0.87 to 1.03)		
M14459 (fHBP) - month 3 (N=25,24,25,22,23,69)	7.4 (4.22 to 13)	1.04 (0.9 to 1.2)		
M14459 (fHBP) - month 6 (N=25,24,25,22,23,70)	1.77 (1.19 to 2.63)	0.99 (0.87 to 1.12)		
M14459 (fHBP) - month 7 (N=25,24,23,22,22,72)	8.18 (5.06 to 13)	0.97 (0.83 to 1.13)		
M14459 (fHBP) - month 12 (N=25,23,21,22,23,71)	2.16 (1.48 to 3.14)	1.03 (0.87 to 1.24)		
M07-0241084 (NHBA) - month 1 (N=24,23,22,20,23,66)	1.55 (1.05 to 2.29)	1.02 (0.87 to 1.19)		
M07-0241084 (NHBA) - month 3 (N=24,23,20,18,22,65)	2.56 (1.67 to 3.93)	1.13 (0.89 to 1.44)		
M07-0241084 (NHBA) - month 6 (N=24,22,21,21,23,65)	1.42 (0.95 to 2.1)	1.2 (0.97 to 1.49)		
M07-0241084 (NHBA) - month 7 (N=24,22,20,21,21,66)	4.15 (2.49 to 6.9)	1.21 (0.96 to 1.51)		
M07-0241084 (NHBA) - month 12 (N=24,22,19,21,23,64)	2.24 (1.44 to 3.46)	1.19 (0.9 to 1.58)		
M01-0240364 (NadA) - month 1 (N=23,24,23,22,23,71)	3.12 (1.41 to 6.91)	1 (0.86 to 1.16)		
M01-0240364 (NadA) - month 3 (N=25,24,23,22,23,69)	196 (86 to 446)	1.28 (1.01 to 1.63)		
M01-0240364 (NadA) - month 6 (N=25,21,24,21,21,70)	6.57 (2.93 to 15)	1.05 (0.9 to 1.23)		
M01-0240364 (NadA) - month 7 (N=24,23,23,22,23,70)	428 (209 to 879)	1.07 (0.92 to 1.25)		
M01-0240364 (NadA) - month 12 (N=23,21,20,22,22,71)	34 (16 to 76)	1.03 (0.87 to 1.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Unsolicited Adverse Events After Vaccination

End point title	Number of Subjects Reporting Unsolicited Adverse Events After Vaccination
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End point description:

Unsolicited AEs were collected with onset from Day 1 through Day 7 After Vaccination.

End point type	Secondary
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End point timeframe:

From Day 1 to Day 7 after vaccination

End point values	3ABCWY	2ABCWY	3ABx2CWY	2ABx2CWY
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	49	24	49
Units: Number of Subjects				
number (not applicable)				
Any AEs	3	6	1	4
At least possibly related AEs	1	4	0	2
SAEs	0	0	0	0
At least possibly related SAEs	0	0	0	0

End point values	3ABCWY+OMV	2ABCWY+OMV	3ABCWYqOMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	48	24	49
Units: Number of Subjects				
number (not applicable)				
Any AEs	2	3	3	2
At least possibly related AEs	1	1	3	0
SAEs	0	0	1	0
At least possibly related SAEs	0	0	1	0

End point values	Men 3B	Men 2B	1ACWY	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	50	73	

Units: Number of Subjects				
number (not applicable)				
Any AEs	2	6	6	
At least possibly related AEs	1	3	3	
SAEs	0	0	0	
At least possibly related SAEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Numbers of Subjects With Other Unsolicited AEs

End point title	Numbers of Subjects With Other Unsolicited AEs
End point description:	Unsolicited AEs were collected from Day 8 After vaccination Through Study Termination.
End point type	Secondary
End point timeframe:	Day 8 After vaccination Through Study Termination

End point values	3ABCWY	2ABCWY	3ABx2CWY	2ABx2CWY
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	48	24	49
Units: Number of Subjects				
number (not applicable)				
Medically attended AEs	5	7	4	10
AEs leading to Withdrawal	0	0	0	0
At least possibly related AEs	0	0	0	0
SAEs	0	0	1	1
At least possibly related SAEs	0	0	0	0

End point values	3ABCWY+OMV	2ABCWY+OMV	3ABCWYqOMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	48	24	49
Units: Number of Subjects				
number (not applicable)				
Medically attended AEs	6	7	2	5
AEs leading to Withdrawal	0	0	0	0
At least possibly related AEs	0	0	0	0
SAEs	0	0	0	1
At least possibly related SAEs	0	0	0	0

End point values	Men 3B	Men 2B	1ACWY	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	50	73	
Units: Number of Subjects				
number (not applicable)				
Medically attended AEs	4	14	15	
AEs leading to Withdrawal	0	0	0	
At least possibly related AEs	0	0	1	
SAEs	0	1	0	
At least possibly related SAEs	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Solicited Local and Systemic Adverse Events (AEs) After Vaccination

End point title	Number of Subjects Reporting Solicited Local and Systemic Adverse Events (AEs) After Vaccination
End point description:	Solicited local and systemic AEs were collected daily for 7 days (day 1 through day 7) after vaccination.
End point type	Secondary
End point timeframe:	From Day 1 to Day 7 after vaccination.

End point values	3ABCWY	2ABCWY	3ABx2CWY	2ABx2CWY
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	48	24	49
Units: Number of Subjects				
number (not applicable)				
Any Solicited Local AEs	18	33	18	35
Injection site erythema	5	13	7	12
Injection site induration	7	14	11	12
Injection site pain	18	33	15	35
Injection site Swelling	5	11	9	10
Any Solicited Systemic AEs	10	33	14	25
Chills	3	10	4	2
Malaise	6	12	7	14
Myalgia	6	23	9	20
Arthralgia	2	6	5	7
Headache	5	20	6	17
Fatigue	3	9	3	9
Nausea	4	6	2	3

Rash	1	2	2	1
Fever ($\geq 38^{\circ}\text{C}$)	3	5	0	3
Any other indicators of reactogenicity	4	8	3	5
Stay home	0	5	0	2

End point values	3ABCWY+OMV	2ABCWY+OMV	3ABCWYqOMV	2ABCWYqOMV
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	48	24	49
Units: Number of Subjects				
number (not applicable)				
Any Solicited Local AEs	23	36	20	30
Injection site erythema	12	11	13	3
Injection site induration	10	17	11	6
Injection site pain	23	35	19	30
Injection site Swelling	10	14	13	5
Any Solicited Systemic AEs	20	23	18	24
Chills	7	7	4	5
Malaise	8	9	7	8
Myalgia	6	18	14	19
Arthralgia	6	5	8	3
Headache	9	11	10	15
Fatigue	5	11	4	7
Nausea	4	6	6	3
Rash	0	1	1	0
Fever ($\geq 38^{\circ}\text{C}$)	3	0	3	1
Any other indicators of reactogenicity	6	3	7	4
Stay home	1	0	3	1

End point values	Men 3B	Men 2B	1ACWY	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	23	50	73	
Units: Number of Subjects				
number (not applicable)				
Any Solicited Local AEs	17	38	53	
Injection site erythema	9	13	19	
Injection site induration	7	14	18	
Injection site pain	17	36	52	
Injection site Swelling	7	14	14	
Any Solicited Systemic AEs	14	34	43	
Chills	5	5	8	
Malaise	5	13	13	
Myalgia	9	21	32	
Arthralgia	2	8	9	
Headache	6	18	27	
Fatigue	3	10	9	
Nausea	2	4	6	

Rash	1	1	2	
Fever ($\geq 38^{\circ}\text{C}$)	2	2	4	
Any other indicators of reactogenicity	3	5	11	
Stay home	0	0	3	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Safety was assessed up to 6 months after vaccination.

Adverse event reporting additional description:

The analyses for serious unsolicited adverse events (SAEs) and adverse events (AEs) were done on the safety population.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	15.0
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Reporting groups

Reporting group title	1ACWY
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Reporting group description:

One dose of MenACWY vaccine followed by one dose of placebo in the primary study and one dose of Tdap in the current study

Reporting group title	Men 3B
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Reporting group description:

Two doses of rMenB vaccine in the primary study and one dose of the same vaccine in the current study

Reporting group title	Men 2B
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Reporting group description:

Two doses of rMenB vaccine in the primary study and one dose of Tdap in the current study.

Reporting group title	3ABCWYqOMV
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Reporting group description:

Two doses of MenABCWY +1/4OMV vaccine in the primary study and one dose of the same vaccine in the current study.

Reporting group title	2ABCWY+OMV
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Reporting group description:

Two doses MenABCWY+OMV vaccine in the primary study and one dose of Tdap in the current study.

Reporting group title	2ABCWYqOMV
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Reporting group description:

Two doses of MenABCWY+ 1/4OMV vaccine in the primary study and one dose of Tdap in the current study.

Reporting group title	3ABx2CWY
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Reporting group description:

Two doses of MenABx2CWY vaccine in the primary study and one dose of the same vaccine in the current study.

Reporting group title	3ABCWY+OMV
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Reporting group description:

Two doses MenABCWY+OMV vaccine in the primary study and one dose of the same vaccine in the current study.

Reporting group title	2ABx2CWY
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Reporting group description:

Two doses of MenABx2CWY vaccine in the primary study and one dose of Tdap in the current study

Reporting group title	3ABCWY
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Reporting group description:

Two doses of MenABCWY vaccine (no outer membrane vesicle {OMV}) in the primary study and one dose of the same vaccine in the current study.

Reporting group title	2ABCWY
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Reporting group description:

Two doses of MenABCWY vaccine (no OMV) in the primary study and one dose of Tdap in the current study.

Serious adverse events	1ACWY	Men 3B	Men 2B
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	1 / 50 (2.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Burns Second Degree			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaccination Complication			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	0 / 50 (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			
Appendiceal Abscess			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	0 / 50 (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
Gastroenteritis			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	0 / 50 (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
Peritonsillar Abscess			
subjects affected / exposed	0 / 73 (0.00%)	0 / 23 (0.00%)	0 / 50 (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	3ABCWYqOMV	2ABCWY+OMV	2ABCWYqOMV
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 48 (0.00%)	1 / 50 (2.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Burns Second Degree			
subjects affected / exposed	0 / 24 (0.00%)	0 / 48 (0.00%)	0 / 50 (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
Vaccination Complication			
subjects affected / exposed	1 / 24 (4.17%)	0 / 48 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendiceal Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 48 (0.00%)	0 / 50 (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
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 48 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 48 (0.00%)	0 / 50 (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	3ABx2CWY	3ABCWY+OMV	2ABx2CWY
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	1 / 49 (2.04%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Burns Second Degree			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 49 (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
Vaccination Complication			

subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 49 (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			
Appendiceal Abscess			
subjects affected / exposed	1 / 24 (4.17%)	0 / 25 (0.00%)	0 / 49 (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
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	0 / 49 (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
Peritonsillar Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 25 (0.00%)	1 / 49 (2.04%)
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	3ABCWY	2ABCWY	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Burns Second Degree			
subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaccination Complication			
subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendiceal Abscess			

subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonsillar Abscess			
subjects affected / exposed	0 / 24 (0.00%)	0 / 49 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	1ACWY	Men 3B	Men 2B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 73 (76.71%)	19 / 23 (82.61%)	40 / 50 (80.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	27 / 73 (36.99%)	7 / 23 (30.43%)	18 / 50 (36.00%)
occurrences (all)	35	8	23
General disorders and administration site conditions			
Chills			
subjects affected / exposed	8 / 73 (10.96%)	5 / 23 (21.74%)	5 / 50 (10.00%)
occurrences (all)	8	5	5
Fatigue			
subjects affected / exposed	9 / 73 (12.33%)	3 / 23 (13.04%)	10 / 50 (20.00%)
occurrences (all)	12	3	11
Injection Site Erythema			
subjects affected / exposed	20 / 73 (27.40%)	10 / 23 (43.48%)	14 / 50 (28.00%)
occurrences (all)	21	10	14
Injection Site Pain			
subjects affected / exposed	52 / 73 (71.23%)	17 / 23 (73.91%)	36 / 50 (72.00%)
occurrences (all)	56	19	38
Injection Site Swelling			

subjects affected / exposed occurrences (all)	16 / 73 (21.92%) 17	8 / 23 (34.78%) 8	14 / 50 (28.00%) 14
Malaise subjects affected / exposed occurrences (all)	13 / 73 (17.81%) 15	5 / 23 (21.74%) 5	13 / 50 (26.00%) 13
Pyrexia subjects affected / exposed occurrences (all)	4 / 73 (5.48%) 4	2 / 23 (8.70%) 2	3 / 50 (6.00%) 5
Injection Site Induration subjects affected / exposed occurrences (all)	19 / 73 (26.03%) 22	8 / 23 (34.78%) 8	15 / 50 (30.00%) 15
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	6 / 73 (8.22%) 6	2 / 23 (8.70%) 3	4 / 50 (8.00%) 4
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	2 / 73 (2.74%) 2	1 / 23 (4.35%) 1	1 / 50 (2.00%) 2
Musculoskeletal and connective tissue disorders Athralgia subjects affected / exposed occurrences (all)	9 / 73 (12.33%) 11	2 / 23 (8.70%) 2	8 / 50 (16.00%) 8
Myalgia subjects affected / exposed occurrences (all)	32 / 73 (43.84%) 37	9 / 23 (39.13%) 9	21 / 50 (42.00%) 23
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	4 / 73 (5.48%) 4	1 / 23 (4.35%) 1	3 / 50 (6.00%) 3

Non-serious adverse events	3ABCWYqOMV	2ABCWY+OMV	2ABCWYqOMV
Total subjects affected by non-serious adverse events subjects affected / exposed	22 / 24 (91.67%)	37 / 48 (77.08%)	38 / 50 (76.00%)
Nervous system disorders Headache			

subjects affected / exposed occurrences (all)	10 / 24 (41.67%) 14	11 / 48 (22.92%) 13	15 / 50 (30.00%) 15
General disorders and administration site conditions			
Chills			
subjects affected / exposed	4 / 24 (16.67%)	8 / 48 (16.67%)	5 / 50 (10.00%)
occurrences (all)	5	8	7
Fatigue			
subjects affected / exposed	4 / 24 (16.67%)	11 / 48 (22.92%)	7 / 50 (14.00%)
occurrences (all)	4	13	9
Injection Site Erythema			
subjects affected / exposed	16 / 24 (66.67%)	12 / 48 (25.00%)	5 / 50 (10.00%)
occurrences (all)	17	12	5
Injection Site Pain			
subjects affected / exposed	19 / 24 (79.17%)	35 / 48 (72.92%)	31 / 50 (62.00%)
occurrences (all)	20	39	32
Injection Site Swelling			
subjects affected / exposed	14 / 24 (58.33%)	14 / 48 (29.17%)	6 / 50 (12.00%)
occurrences (all)	15	16	6
Malaise			
subjects affected / exposed	8 / 24 (33.33%)	9 / 48 (18.75%)	8 / 50 (16.00%)
occurrences (all)	9	11	9
Pyrexia			
subjects affected / exposed	5 / 24 (20.83%)	0 / 48 (0.00%)	1 / 50 (2.00%)
occurrences (all)	5	0	1
Injection Site Induration			
subjects affected / exposed	13 / 24 (54.17%)	17 / 48 (35.42%)	8 / 50 (16.00%)
occurrences (all)	14	18	8
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	6 / 24 (25.00%)	7 / 48 (14.58%)	3 / 50 (6.00%)
occurrences (all)	8	7	4
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 24 (4.17%)	1 / 48 (2.08%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			

Athralgia			
subjects affected / exposed	8 / 24 (33.33%)	5 / 48 (10.42%)	3 / 50 (6.00%)
occurrences (all)	8	5	3
Myalgia			
subjects affected / exposed	14 / 24 (58.33%)	18 / 48 (37.50%)	19 / 50 (38.00%)
occurrences (all)	14	18	20
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 24 (4.17%)	1 / 48 (2.08%)	2 / 50 (4.00%)
occurrences (all)	1	1	2

Non-serious adverse events	3ABx2CWY	3ABCWY+OMV	2ABx2CWY
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 24 (83.33%)	23 / 25 (92.00%)	36 / 49 (73.47%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 24 (25.00%)	9 / 25 (36.00%)	17 / 49 (34.69%)
occurrences (all)	6	11	21
General disorders and administration site conditions			
Chills			
subjects affected / exposed	4 / 24 (16.67%)	7 / 25 (28.00%)	2 / 49 (4.08%)
occurrences (all)	4	7	3
Fatigue			
subjects affected / exposed	3 / 24 (12.50%)	5 / 25 (20.00%)	9 / 49 (18.37%)
occurrences (all)	3	6	9
Injection Site Erythema			
subjects affected / exposed	7 / 24 (29.17%)	13 / 25 (52.00%)	14 / 49 (28.57%)
occurrences (all)	7	14	15
Injection Site Pain			
subjects affected / exposed	15 / 24 (62.50%)	23 / 25 (92.00%)	35 / 49 (71.43%)
occurrences (all)	15	24	38
Injection Site Swelling			
subjects affected / exposed	9 / 24 (37.50%)	11 / 25 (44.00%)	11 / 49 (22.45%)
occurrences (all)	9	12	13
Malaise			
subjects affected / exposed	7 / 24 (29.17%)	8 / 25 (32.00%)	14 / 49 (28.57%)
occurrences (all)	7	8	15

Pyrexia subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	3 / 25 (12.00%) 3	3 / 49 (6.12%) 3
Injection Site Induration subjects affected / exposed occurrences (all)	11 / 24 (45.83%) 12	12 / 25 (48.00%) 13	13 / 49 (26.53%) 14
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	4 / 25 (16.00%) 4	3 / 49 (6.12%) 3
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	0 / 25 (0.00%) 0	1 / 49 (2.04%) 1
Musculoskeletal and connective tissue disorders Athralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 5 9 / 24 (37.50%) 9	6 / 25 (24.00%) 6 15 / 25 (60.00%) 18	7 / 49 (14.29%) 8 20 / 49 (40.82%) 22
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 25 (4.00%) 1	4 / 49 (8.16%) 4

Non-serious adverse events	3ABCWY	2ABCWY	
Total subjects affected by non-serious adverse events subjects affected / exposed	20 / 24 (83.33%)	38 / 49 (77.55%)	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 7	20 / 49 (40.82%) 25	
General disorders and administration site conditions Chills subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 4	10 / 49 (20.41%) 11	

Fatigue			
subjects affected / exposed	3 / 24 (12.50%)	9 / 49 (18.37%)	
occurrences (all)	3	10	
Injection Site Erythema			
subjects affected / exposed	5 / 24 (20.83%)	16 / 49 (32.65%)	
occurrences (all)	6	16	
Injection Site Pain			
subjects affected / exposed	18 / 24 (75.00%)	33 / 49 (67.35%)	
occurrences (all)	19	36	
Injection Site Swelling			
subjects affected / exposed	5 / 24 (20.83%)	11 / 49 (22.45%)	
occurrences (all)	6	11	
Malaise			
subjects affected / exposed	6 / 24 (25.00%)	12 / 49 (24.49%)	
occurrences (all)	6	14	
Pyrexia			
subjects affected / exposed	3 / 24 (12.50%)	6 / 49 (12.24%)	
occurrences (all)	3	8	
Injection Site Induration			
subjects affected / exposed	7 / 24 (29.17%)	16 / 49 (32.65%)	
occurrences (all)	7	16	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 24 (16.67%)	6 / 49 (12.24%)	
occurrences (all)	4	7	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 24 (4.17%)	2 / 49 (4.08%)	
occurrences (all)	1	2	
Musculoskeletal and connective tissue disorders			
Athralgia			
subjects affected / exposed	2 / 24 (8.33%)	6 / 49 (12.24%)	
occurrences (all)	2	6	
Myalgia			
subjects affected / exposed	6 / 24 (25.00%)	23 / 49 (46.94%)	
occurrences (all)	7	27	

Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 24 (8.33%) 2	2 / 49 (4.08%) 2	
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More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 August 2011	After study completion, once the database is locked and the study is unblinded, subjects randomized in study Group V will be offered the Menveo vaccination (in countries where it is licensed), out of the scope of the trial.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported