Clinical trial results:
A Phase 2, Open-Label, Single-Center, Extension Study Evaluating Antibody Persistence Compared to Naive Children and Safety, Tolerability and Immunogenicity of a Booster Dose of Novartis rMenB±OMV NZ Vaccine in Healthy UK Children Who Previously Received a Three-Dose Series of the Novartis Vaccine as Infants in Study V72P9.

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

Summary

EudraCT number	2009-013075-21
Trial protocol	GB
Global end of trial date	23 May 2012

Results information

Result version number	v2 (current)
This version publication date	04 June 2016
First version publication date	01 April 2015
Version creation reason	• Correction of full data set re-QC of the study is needed because of EudraCT system glitch and updates to results are required.

Trial information

Trial identification

Sponsor protocol code	V72P9E1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01026974
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, RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines, RegistryContactVaccinesUS@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000139-PIP01-07
Does article 45 of REGULATION (EC) No	No

1901/2006 apply to this trial?	
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	21 November 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 May 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Immunogenicity Objective: To explore bactericidal antibody persistence in children at 40 months of age who previously received three doses of rMenB (recombinant Meningococcal B) or Meningococcal B Recombinant Vaccine ± Outer Membrane Vesicles (OMV) (rMenB+OMV NZ) as infants in parent study V72P9.
Safety Objectives: To assess the safety and tolerability of a booster dose of rMenB or rMenB+OMV NZ administered to children at 40 months of age who previously received three doses of the same vaccine as infants in parent study V72P9.

Protection of trial subjects:

The trial was conducted in compliance with the protocol, ethical principles that have their origin in the Declaration of Helsinki, that are consistent with good clinical practice (GCP) according to International Conference on Harmonisation (ICH) guidelines and the applicable regulatory requirements. A comprehensive review of rMenB±OMV NZ was contained in the investigator's brochure (IB) supplied by Novartis Vaccines and Diagnostics; this document had to be reviewed prior to initiating the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	20 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	120
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from a single center.

Pre-assignment

Screening details:

All enrolled subjects were included in the trial.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	4rMenB

Arm description:

Subjects received three primary doses of rMenB vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study V72P9 and one booster dose of rMenB vaccine at 40 months of age in the present study.

Arm type	Experimental
Investigational medicinal product name	rMenB
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Each dose 0.5 mL of injectable solution was administered intramuscularly.

Arm title	4rMenB+OMV NZ

Arm description:

Subjects received three primary doses of rMenB+OMV NZ vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study and one booster dose of rMenB+OMV NZ vaccine at 40 months of age in the present study.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Each dose 0.5 mL of injectable solution was administered intramuscularly.

Arm title	Naive_4042

Arm description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 40 and 42 months of age in the present study.

Arm type	Experimental

Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Each dose 0.5 mL of injectable solution was administered intramuscularly.

Arm title	Naive_6062

Arm description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 60 and 62 months of age in the present study.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Each dose 0.5 mL of injectable solution was administered intramuscularly.

Number of subjects in period 1	4rMenB	4rMenB+OMV NZ	Naive_4042
Started	16	14	41
Completed	15	12	29
Not completed	1	2	12
Consent withdrawn by subject	-	1	7
Inappropriate enrollment	-	-	1
Adverse event	-	-	-
Lost to follow-up	1	1	4

Number of subjects in period 1	Naive_6062
Started	49
Completed	46
Not completed	3
Consent withdrawn by subject	2
Inappropriate enrollment	-
Adverse event	1
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	4rMenB
Reporting group description:	
Subjects received three primary doses of rMenB vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study V72P9 and one booster dose of rMenB vaccine at 40 months of age in the present study.	

Reporting group title	4rMenB+OMV NZ
Reporting group description:	
Subjects received three primary doses of rMenB+OMV NZ vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study and one booster dose of rMenB+OMV NZ vaccine at 40 months of age in the present study.	
Reporting group title	Naive_4042
Reporting group description:	
Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 40 and 42 months of age in the present study.	
Reporting group title	Naive_6062
Reporting group description:	
Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 60 and 62 months of age in the present study.	

Reporting group values	4rMenB	4rMenB+OMV NZ	Naive_4042
Number of subjects	16	14	41
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)	16	14	41
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: months			
arithmetic mean	42.8	43.1	41.7
standard deviation	± 1.1	± 0.9	± 1.7
Gender categorical Units: Subjects			
Female	8	11	22
Male	8	3	19

Reporting group values	Naive_6062	Total	
Number of subjects	49	120	

Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	49	120	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: months			
arithmetic mean	61.3		
standard deviation	± 0.7	-	
Gender categorical Units: Subjects			
Female	21	62	
Male	28	58	

End points

End points reporting groups

Reporting group title	4rMenB

Reporting group description:

Subjects received three primary doses of rMenB vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study V72P9 and one booster dose of rMenB vaccine at 40 months of age in the present study.

Reporting group title	4rMenB+OMV NZ

Reporting group description:

Subjects received three primary doses of rMenB+OMV NZ vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study and one booster dose of rMenB+OMV NZ vaccine at 40 months of age in the present study.

Reporting group title	Naive_4042

Reporting group description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 40 and 42 months of age in the present study.

Reporting group title	Naive_6062

Reporting group description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 60 and 62 months of age in the present study.

Subject analysis set title	Full Analysis Set (FAS) population
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects in the enrolled population who are randomized and actually receive at least one rMenB±OMV NZ, and provided at least one evaluable serum sample both before and after baseline with exception of the analysis of persistence data, where only a sample before rMenB±OMV NZ vaccination is required.

Subject analysis set title	Modified Intention-to-treat (MITT) population
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

All subjects in the enrolled population who are randomized and actually receive at least one rMenB±OMV NZ, and provide at least one evaluable serum sample both before and after baseline with exception of the analysis of persistence data, where only a sample before rMenB±OMV NZ vaccination is required.

Subject analysis set title	Safety Population
Subject analysis set type	Safety analysis

Subject analysis set description:

All subjects who received at least one rMenB±OMV NZ vaccination and provided post-baseline safety data.

Primary: 1.Persistence of human complement Serum Bactericidal Assay antibody Titers in Children (at 40 Months of Age), Twenty-eight Months After Completing Primary Vaccination.

End point title	1.Persistence of human complement Serum Bactericidal Assay antibody Titers in Children (at 40 Months of Age), Twenty-eight Months After Completing Primary Vaccination.[1][2]

End point description:

The geometric mean antibody titers (GMTs) against Neisseria meningitidis serogroup B in children (at 40 months of age); twenty-eight months after completion of primary vaccination with either rMenB or rMenB+OMV NZ vaccines, are compared with the GMTs in vaccine-naïve children.

End point type	Primary

End point timeframe:

28 months after primary vaccination; Baseline for Naïve

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 analysis is associated with this endpoint.

[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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	14	40	
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain (N = 14,14,39)	1.26 (0.9 to 1.76)	2.55 (1.15 to 5.66)	1.08 (0.97 to 1.2)	
5/99 strain (N = 14,14,40)	41 (18 to 95)	29 (18 to 47)	1 (1 to 1)	
NZ98/254 strain (N = 15,14,39)	1 (1 to 1)	1.74 (0.91 to 3.33)	1 (1 to 1)	
M10713 strain (N = 14,14,40)	3.6 (1.32 to 9.84)	7.11 (3.61 to 14)	4.82 (2.9 to 8)	

Statistical analyses

No statistical analyses for this end point

Primary: 2. Percentage of Subjects With Persisting hSBA antibodies Titers ≥4, Twenty-eight Months After Completing Primary Vaccination.

End point title	2. Percentage of Subjects With Persisting hSBA antibodies Titers ≥4, Twenty-eight Months After Completing Primary Vaccination.[3][4]

End point description:

The percentages of subjects with persisting hSBA titers ≥4, against N meningitidis serogroup B at 40 months of age; twenty-eight months after completion of primary vaccination with either rMenB or rMenB+OMV NZ as compared to the vaccine-naive children are reported.The serum bactericidal antibodies directed against serogroup B meningococci, are measured by hSBA.
Analysis was done on MITT population.

End point type	Primary

End point timeframe:

28 months after primary vaccination; Baseline for Naive

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 analysis is associated with this endpoint.

[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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	14	40	
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 14,14,39)	14 (2 to 43)	36 (13 to 65)	3 (0.065 to 13)	
5/99 strain (N = 14,14,40)	93 (66 to 100)	100 (77 to 100)	0 (0 to 9)	
NZ98/254 strain (N = 15,14,39)	0 (0 to 22)	14 (2 to 43)	0 (0 to 9)	
M10713 strain (N = 14,14,40)	29 (8 to 58)	79 (49 to 95)	53 (36 to 68)	

Statistical analyses

No statistical analyses for this end point

Primary: 3. Number of Subjects Reporting Solicited Local and Systemic Adverse Events After a Booster Dose of rMenB or rMenB+OMV NZ Vaccine at Forty Months of Age.

End point title	3. Number of Subjects Reporting Solicited Local and Systemic Adverse Events After a Booster Dose of rMenB or rMenB+OMV NZ Vaccine at Forty Months of Age.[5][6]

End point description:

The safety and tolerability of a single booster dose of rMenB or rMenB+OMV NZ vaccine in 40 month old children who had previously received three primary doses of the same vaccine as infants in parent study was assessed in terms of number of subjects with solicited local and systemic reactions following vaccination and compared to tolerability in vaccine-naive children who received first catch-up dose of rMenB+OMV NZ at 40 months of age.
Analysis was done on the Safety population.

End point type	Primary

End point timeframe:

Day 1 to Day 7 [after booster vaccination /post dose 1 for naive]

Notes:

[5] - 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 analysis is associated with this endpoint.

[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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	16	14	39	
Units: Number of Subjects				
Any Local	14	14	38	
Injection-site pain	10	12	34	
Injection-site erythema	13	14	36	
Injection-site swelling	9	6	10	
Injection-site induration	11	5	17	
Any Systemic	12	11	30	
Change in eating habits	5	5	13	
Sleepiness	6	6	20	

Vomiting	0	2	1	
Diarrhea	2	1	2	
Irritability	8	11	24	
Headache	2	1	4	
Arthralgia	2	3	9	
Rash	2	1	2	
Fever (≥38°C)	4	1	6	
Other	6	10	21	
Temperature (≥40°C)	0	0	1	
Antipyretic preventive medication used	4	9	19	
Antipyretic treatment medication used	3	1	5	
Medically attended fever	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: 4. HSBA antibody Titers in Children After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age

End point title	4. HSBA antibody Titers in Children After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age[7]

End point description:

The serum bacterial antibody response one month after a booster dose of rMenB or rMenB+OMV NZ vaccine was given to children at 40 months of age and was compared with the antibody titers following one catch-up dose rMenB+OMV NZ vaccine given at 40 months to vaccine-naive subjects and reported as GMTs.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post booster /1 month post dose 1 for Naïve

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	14	39	
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain (N = 13,14,39)	100 (50 to 200)	114 (59 to 222)	8.89 (5.83 to 14)	
5/99 strain	1007 (445 to 2277)	926 (432 to 1988)	27 (16 to 44)	
NZ98/254 strain	2.15 (0.88 to 5.23)	32 (14 to 71)	1.91 (1.35 to 2.71)	
M10713 strain (N = 13,14,39)	10 (3.43 to 30)	23 (13 to 41)	6.04 (3.73 to 9.79)	

Statistical analyses

No statistical analyses for this end point

Secondary: 5. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4 After Receiving a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine at 40 Months of Age

End point title	5. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4 After Receiving a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine at 40 Months of Age[8]

End point description:

The percentages of subjects with hSBA titers ≥4 against N meningitidis serogroup B one month after receiving a single booster dose of rMenB or rMenB+OMV NZ vaccine at 40 months of age, is compared with hSBA response following one catch-up.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post-booster/ 1 month post-dose 1 for Naïve

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	14	39	
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 13, 14, 39)	100 (75 to 100)	100 (77 to 100)	72 (55 to 85)	
5/99 strain	100 (77 to 100)	100 (77 to 100)	87 (73 to 96)	
NZ98/254 strain	21 (5 to 51)	93 (66 to 100)	23 (11 to 39)	
M10713 strain (N = 13, 14, 39)	69 (39 to 91)	93 (66 to 100)	62 (45 to 77)	

Statistical analyses

No statistical analyses for this end point

Secondary: 6. Percentage of Subjects With a four-fold Increase in Antibody Titers After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age

End point title	6. Percentage of Subjects With a four-fold Increase in Antibody Titers After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age[9]

End point description:

The percentages of subjects with four-fold increase in hSBA titers over baseline against N meningitidis serogroup B, one month after receiving a single booster dose of rMenB or rMenB+OMV NZ vaccine at 40 months of age, and compared with four-fold increase in hSBA titers following one catch-up dose of rMenB+OMV NZ vaccine given at 40 months to vaccine-naive subjects.
Baseline was defined as either the time that the (first) booster dose was given (i.e. at 40 months of age) or the time of the first vaccination (i.e. at 40 months of age) for Naive_4042 group.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post booster / 1 month post dose 1 for Naive

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	14	38	
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 11,14,37)	100 (72 to 100)	93 (66 to 100)	54 (37 to 71)	
5/99 strain (N = 12,14,38)	100 (74 to 100)	100 (77 to 100)	76 (60 to 89)	
NZ98/254 strain (N = 13,14,37)	23 (5 to 54)	71 (42 to 92)	11 (3 to 25)	
M10713 strain (N = 11,14,38)	18 (2 to 52)	36 (13 to 65)	5 (1 to 18)	

Statistical analyses

No statistical analyses for this end point

Secondary: 7. Persistence of Serum Bactericidal Antibody Titers in Children (at 60 Months of Age), Twenty Months After Receiving a Booster Dose of rMenB or rMenB+OMV NZ Vaccine

End point title	7. Persistence of Serum Bactericidal Antibody Titers in Children (at 60 Months of Age), Twenty Months After Receiving a Booster Dose of rMenB or rMenB+OMV NZ Vaccine[10]

End point description:

The persisting serum bactericidal antibody titers in children (at 60 months of age), twenty months after receiving a booster dose of either rMenB or rMenB+OMV NZ vaccine (at 40 months of age) is compared with the antibody titers in vaccine -naïve subjects of the same age and reported as GMTs.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

20 months post booster/ Baseline for Naive

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_6062	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	12	46	
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain (N = 9,12,46)	9.37 (2.47 to 36)	4.69 (1.98 to 11)	1.09 (0.96 to 1.25)	
5/99 strain (N = 9,11,46)	334 (186 to 599)	119 (56 to 252)	1.17 (0.96 to 1.42)	
NZ98/254 strain (N = 10,12,46)	1 (1 to 1)	1.63 (0.86 to 3.08)	1 (1 to 1)	
M10713 strain (N = 8,11,45)	4.96 (1.03 to 24)	5.51 (2.19 to 14)	8.09 (5.13 to 13)	

Statistical analyses

No statistical analyses for this end point

Secondary: 8. Percentage of Subjects With Persisting Serum Bactericidal Antibody Titers ≥4, Twenty Months After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine.

End point title	8. Percentage of Subjects With Persisting Serum Bactericidal Antibody Titers ≥4, Twenty Months After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine.[11]

End point description:

The percentage of subjects (60 months of age) with persisting hSBA titers ≥4, twenty months after receiving a booster dose of either rMenB or rMenB+OMV NZ vaccine (at 40 months of age) are compared with hSBA response in vaccine-naïve subjects of the same age.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

20 months post booster/ Baseline for Naive

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_6062	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	12	46	
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 9,12,46)	67 (30 to 93)	67 (35 to 90)	4 (1 to 15)	
5/99 strain (N = 9,11,46)	100 (66 to 100)	100 (72 to 100)	4 (1 to 15)	
NZ98/254 strain	0 (0 to 31)	17 (2 to 48)	0 (0 to 8)	
M10713 strain (N = 8,11,45)	50 (16 to 84)	45 (17 to 77)	67 (51 to 80)	

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4 Following Two Doses of rMenB+OMV NZ Vaccine Given two Months Apart, Either at 40 or 60 Months of Age

End point title	9. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4 Following Two Doses of rMenB+OMV NZ Vaccine Given two Months Apart, Either at 40 or 60 Months of Age[12]

End point description:

The percentage of subjects with hSBA titers ≥4 after two catch-up doses of rMenB+OMV NZ vaccine when given either at- 40 & 42 months or 60 & 62 months of age is reported.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post vaccine dose two

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 analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	35		
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 30,34)	100 (88 to 100)	100 (90 to 100)		
5/99 strain (N = 31,34)	100 (89 to 100)	100 (90 to 100)		
NZ98/254 strain	90 (74 to 98)	89 (73 to 97)		
M10713 strain (N = 29,33)	72 (53 to 87)	97 (84 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: 10. Serum Bactericidal Antibody Titers in Children Following Two Doses of rMenB+OMV NZ Vaccine Given two Months Apart, Either at 40 or 60 Months of Age.

End point title	10. Serum Bactericidal Antibody Titers in Children Following Two Doses of rMenB+OMV NZ Vaccine Given two Months Apart, Either at 40 or 60 Months of Age.[13]

End point description:

The serum bactericidal antibody response in children after two catch-up doses of rMenB+OMV NZ vaccine when given either at- 40 & 42 months or 60 & 62 months of age are reported as GMTs.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post -vaccine dose two

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 analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	35		
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain (N = 30,34)	74 (57 to 94)	83 (67 to 103)		
5/99 strain (N = 31,34)	247 (188 to 323)	331 (254 to 432)		
NZ98/254 strain (N = 30,35)	16 (11 to 23)	14 (9.81 to 21)		
M10713 strain (N = 29,33)	8.91 (5.19 to 15)	44 (33 to 57)		

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Percentage of Subjects With a four-fold Increase in Antibody Titers After Two Catch up Doses of rMenB+OMV NZ Vaccine Given two Months Apart Either at 40 or 60 Months of Age

End point title	11. Percentage of Subjects With a four-fold Increase in Antibody Titers After Two Catch up Doses of rMenB+OMV NZ Vaccine Given two Months Apart Either at 40 or 60 Months of Age[14]

End point description:

The percentages of subjects with four-fold increase in hSBA titers over baseline against N meningitidis serogroup B one month after receiving a two catch-up doses of rMenB+OMV NZ vaccine either at 40 and 42 months or 60 and 62 months of age.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post vaccine dose two

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 analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	35		
Units: Percentage of Subjects				
number (confidence interval 95%)				
44/76-SL strain (N = 29,34)	100 (88 to 100)	100 (90 to 100)		
5/99 strain (N = 31,34)	100 (89 to 100)	100 (90 to 100)		
NZ98/254 strain (N = 30,35)	73 (54 to 88)	69 (51 to 83)		

M10713 strain (N = 29,32)	24 (10 to 44)	53 (35 to 71)		

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Persistence of Serum Bactericidal Antibody Titers in Children (at 60 Months), Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.

End point title	12. Persistence of Serum Bactericidal Antibody Titers in Children (at 60 Months), Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.[15]

End point description:

The serum bactericidal antibody response in children at 60 months of age who had received two catch-up doses of rMenB+OMV NZ vaccine at- 40 & 42 months age is reported as GMTs.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

18 months post vaccination dose two

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 analysis is associated with this endpoint.

End point values	Naive_4042			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain	2.73 (1.54 to 4.84)			
5/99 strain	24 (16 to 35)			
NZ98/254 strain	1 (1 to 1)			
M10713 strain (N=23)	14 (6.78 to 27)			

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4, Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.

End point title	13. Percentage of Subjects With Serum Bactericidal Antibody Titers ≥4, Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.[16]

End point description:

Persisting hSBA titers ≥4 in children at 60 months of age, who had received two catchup doses of

rMenB+OMV NZ vaccine at 40 & 42 months age is reported.
Analysis was done on MITT population

End point type	Secondary

End point timeframe:

18 months post vaccine dose two

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 analysis is associated with this endpoint.

End point values	Naive_4042			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Titers				
geometric mean (confidence interval 95%)				
44/76-SL strain	38 (19 to 59)			
5/99 strain	100 (86 to 100)			
NZ98/254 strain	0 (0 to 14)			
M10713 strain (N=23)	83 (61 to 95)			

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Persistence of Geometric Mean Antibody Concentrations in Children (at 40 Months of Age), Twenty Eight Months After Completing Primary Vaccination.

End point title	14. Persistence of Geometric Mean Antibody Concentrations in Children (at 40 Months of Age), Twenty Eight Months After Completing Primary Vaccination.[17]

End point description:

The persisting geometric mean antibody concentrations (GMCs) against vaccine antigen 287-953 in children (at 40 months of age), twenty-eight months after completion of primary vaccination with either rMenB or rMen+OMV NZ vaccines, are compared with the GMCs in vaccine-naive children.
GMCs against vaccine antigen 287-953 were measured using enzyme linked immunosorbent assay (ELISA).
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

28 months after primary vaccination/ Baseline for Naive

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	14	39	
Units: Concentration (IU/mL)				
geometric mean (confidence interval 95%)				
287-953 Strain	86 (43 to 173)	103 (61 to 174)	27 (22 to 35)	

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Geometric Mean Antibody Concentrations in Children, After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age.

End point title	15. Geometric Mean Antibody Concentrations in Children, After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age.[18]

End point description:

The GMCs against vaccine antigen 287-953, in children one month after receiving a single booster dose of either rMenB or rMen+OMV NZ vaccine , is compared with GMCs following one catch-up dose of rMenB+ OMV NZ in children at 40 months.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post booster /1 month post dose 1 for Naive

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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	15	14	39	
Units: Concentration (IU/mL)				
geometric mean (confidence interval 95%)				
287-953 Strain	5187 (2924 to 9204)	3662 (2065 to 6491)	83 (52 to 133)	

Statistical analyses

No statistical analyses for this end point

Secondary: 16. Geometric Mean Antibody Concentrations (GMCs) in Children (at 60 Months of Age), Twenty Months After Receiving a Booster Dose of rMenB or rMenB+OMV NZ Vaccine

End point title	16. Geometric Mean Antibody Concentrations (GMCs) in Children (at 60 Months of Age), Twenty Months After Receiving

	a Booster Dose of rMenB or rMenB+OMV NZ Vaccine[19]

End point description:

The persisting GMCs against vaccine antigen 287-953 in children (at 60 months of age), twenty months after receiving a booster dose of either rMenB or rMenB+OMV NZ vaccine (at 40 months), are compared with GMCs in vaccine-naïve children of same age.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

20 months post booster/ Baseline for Naive

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_6062	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	12	46	
Units: Concentration (IU/mL)				
geometric mean (confidence interval 95%)				
287-953 Strain	772 (395 to 1512)	358 (201 to 640)	25 (19 to 33)	

Statistical analyses

No statistical analyses for this end point

Secondary: 17. Geometric Mean Antibody Concentrations in Children After Two Doses of rMenB+OMV NZ Vaccine Given Two Months Apart, Either at 40 Months or 60 Months of Age.

End point title	17. Geometric Mean Antibody Concentrations in Children After Two Doses of rMenB+OMV NZ Vaccine Given Two Months Apart, Either at 40 Months or 60 Months of Age.[20]

End point description:

The GMCs against vaccine antigen 287-953 in children after two catch-up doses of rMenB+OMV NZ vaccine when given either at- 40 & 42 months or 60 & 62 months of age are reported.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post vaccine dose two

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	35		
Units: Concentration (IU/mL)				
geometric mean (confidence interval 95%)				
287-953 Strain	612 (329 to 1139)	2164 (1663 to 2817)		

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Geometric Mean Antibody Concentrations in Children (at 60 Months), Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.

End point title	18. Geometric Mean Antibody Concentrations in Children (at 60 Months), Eighteen Months After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine.[21]

End point description:

Persistence of GMCs against vaccine antigen 287-953 in children (60 months of age), eighteen months after two catch-up doses of rMenB+OMV NZ vaccine given at 40 months of age.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

18 months post vaccine dose two

Notes:

[21] - 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 analysis is associated with this endpoint.

End point values	Naive_4042			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Concentration (IU/mL)				
geometric mean (confidence interval 95%)				
287-953 Strain	87 (63 to 120)			

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percentage of Subjects With Four Fold Increase in Geometric Mean Antibody Concentrations , After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age.

End point title	19. Percentage of Subjects With Four Fold Increase in Geometric Mean Antibody Concentrations , After a Single Booster Dose of rMenB or rMenB+OMV NZ Vaccine Given at 40 Months of Age.[22]

End point description:

The percentage of subjects with four fold increase in GMCs over baseline against vaccine antigen 287-953 one month after receiving a single booster dose of either rMenB or rMen+OMV NZ vaccine, is compared with responses following one catch-up dose of rMenB+OMV NZ in children at 40 months.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post booster /1 month post dose 1 for Naive

Notes:

[22] - 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 analysis is associated with this endpoint.

End point values	4rMenB	4rMenB+OMV NZ	Naive_4042	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	14	38	
Units: Percentage of Subjects				
number (confidence interval 95%)				
287-953 Strain	100 (77 to 100)	100 (77 to 100)	21 (10 to 37)	

Statistical analyses

No statistical analyses for this end point

Secondary: 20. Percentage of Subjects With four-fold Increase in GMCs of Antibody, After Two Catch-up Doses of rMenB+OMV NZ Vaccine Given Two Months Apart Either at 40 or 60 Months of Age.

End point title	20. Percentage of Subjects With four-fold Increase in GMCs of Antibody, After Two Catch-up Doses of rMenB+OMV NZ Vaccine Given Two Months Apart Either at 40 or 60 Months of Age.[23]

End point description:

The percentages of subjects with four-fold increase in GMCs over baseline against vaccine antigen 287-953, one month after receiving a two catch-up doses of rMenB+OMV NZ vaccine either at 40 & 42 months or 60 & 62 months of age.
Analysis was done on MITT population.

End point type	Secondary

End point timeframe:

1 month post vaccine dose two

Notes:

[23] - 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 analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	35		
Units: Percentage of Subjects				
geometric mean (confidence interval 95%)				
287-953 Strain	77 (59 to 90)	97 (85 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: 21. Number of Children Reporting Solicited Local and Systemic Adverse Events After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine two Months Apart, Either at 40 or 60 Months of Age.

End point title	21. Number of Children Reporting Solicited Local and Systemic Adverse Events After Receiving Two Catch-up Doses of rMenB+OMV NZ Vaccine two Months Apart, Either at 40 or 60 Months of Age.[24]

End point description:

The safety and tolerability of a two doses of rMenB+OMV NZ vaccine in children when given either at 40 & 42 months or 60 & 62 months of age is assessed in terms of number of subjects with solicited local and systemic reactions following vaccination.
Analysis was done on the Safety population

End point type	Secondary

End point timeframe:

Day 1 to Day 7 after each vaccination

Notes:

[24] - 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 analysis is associated with this endpoint.

End point values	Naive_4042	Naive_6062		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	48		
Units: Number of subjects				
Any Local	39	48		
Injection-site pain	38	46		
Injection-site erythema	38	46		
Injection-site swelling	19	32		
Injection-site induration	26	28		
Any Systemic	35	44		
Change in eating habits	20	15		
Sleepiness	26	26		
Vomiting	4	7		
Diarrhea	4	4		
Irritability	29	29		
Headache	8	12		
Arthralgia	13	24		
Rash	3	5		
Fever (≥38°C)	10	10		
Antipyretic Preventive medication used	24	29		
Antipyretic Treatment medication used	8	12		
Temperature(≥40°C)	1	0		

Medically attended fever	1	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Throughout the study

Adverse event reporting additional description:

Solicited Adverse Events (AEs) were collected from Day 1 to Day 7 after each vaccination, Serious Adverse Events (SAEs) and other unsolicited AEs were collected throughout the study [approximately 20 months for Groups rMenB; rMenB+OMV NZ and Naive_4042 and Day 1 to Day 91 for Naive_6062 group].

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.0

Reporting groups

Reporting group title	4rMenB

Reporting group description:

Subjects received three primary doses of rMenB vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study and one booster dose of rMenB vaccine at 40 months of age in the present study.

Reporting group title	4rMenB+OMV NZ

Reporting group description:

Subjects received three primary doses of rMenB+OMV NZ vaccine (at the age of 6-8 months; 2 months after and at 12 months) in parent study and one booster dose of rMenB+OMV NZ vaccine at 40 months of age in the present study.

Reporting group title	Naive_4042

Reporting group description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 40 and 42 months of age in the present study.

Reporting group title	Naive_6062

Reporting group description:

Vaccine-naive subjects who received two catch-up doses of rMenB+OMV NZ vaccine at 60 and 62 months of age in the present study.

Serious adverse events	4rMenB	4rMenB+OMV NZ	Naive_4042
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	1 / 14 (7.14%)	4 / 41 (9.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile convulsion	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Lymphadenitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (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
Gastrointestinal disorders			
Vomiting	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	0 / 41 (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			
Croup infectious	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Upper respiratory tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	1 / 41 (2.44%)
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	Naive_6062		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 48 (2.08%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Febrile convulsion	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Lymphadenitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Vomiting	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used:			

MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Croup infectious	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15.0 and AE occurences number all & related, fatalaties number all & related were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 48 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	4rMenB	4rMenB+OMV NZ	Naive_4042
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 16 (93.75%)	14 / 14 (100.00%)	41 / 41 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumor benign	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Ear tube insertion	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Induration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	2 / 41 (4.88%)
occurrences (all)	0	1	2
Injection site erythema	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	13 / 16 (81.25%)	14 / 14 (100.00%)	40 / 41 (97.56%)
occurrences (all)	13	14	74
Injection site induration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used:			

MedDRA 17.1			
subjects affected / exposed	11 / 16 (68.75%)	5 / 14 (35.71%)	26 / 41 (63.41%)
occurrences (all)	14	6	39
Pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Swelling	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Injection site pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	10 / 16 (62.50%)	12 / 14 (85.71%)	38 / 41 (92.68%)
occurrences (all)	13	13	73
Injection site swelling	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	9 / 16 (56.25%)	6 / 14 (42.86%)	20 / 41 (48.78%)
occurrences (all)	9	6	27
Pyrexia	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	4 / 16 (25.00%)	1 / 14 (7.14%)	11 / 41 (26.83%)
occurrences (all)	4	1	11
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

Cough	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	3 / 41 (7.32%)
occurrences (all)	1	0	3
Respiratory disorder	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Irritability	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	8 / 16 (50.00%)	11 / 14 (78.57%)	29 / 41 (70.73%)
occurrences (all)	8	14	50
Eating disorder	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	5 / 16 (31.25%)	5 / 14 (35.71%)	20 / 41 (48.78%)
occurrences (all)	5	5	26
Injury, poisoning and procedural complications			
Skin Abrasion (Excoriation)	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Laceration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	8 / 41 (19.51%)
occurrences (all)	2	1	9
Somnolence	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	6 / 16 (37.50%)	6 / 14 (42.86%)	26 / 41 (63.41%)
occurrences (all)	6	8	38
Blood and lymphatic system disorders			
Lymphadenopathy	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Ear pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Abdominal pain upper	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Gastritis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Diarrhoea	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	4 / 41 (9.76%)
occurrences (all)	2	1	4
Vomiting	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all		

	number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	2 / 14 (14.29%)	6 / 41 (14.63%)
occurrences (all)	0	2	7
Skin and subcutaneous tissue disorders			
Erythema	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	2	1	0
Rash macular	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Rash	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	5 / 41 (12.20%)
occurrences (all)	2	1	5
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 16 (12.50%)	3 / 14 (21.43%)	13 / 41 (31.71%)
occurrences (all)	2	3	18
Infections and infestations			
Conjunctivitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 16 (6.25%)	1 / 14 (7.14%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
Ear infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 16 (12.50%)	1 / 14 (7.14%)	3 / 41 (7.32%)
occurrences (all)	3	1	7
Rhinitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	0 / 14 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
Tonsillitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 16 (0.00%)	1 / 14 (7.14%)	4 / 41 (9.76%)
occurrences (all)	0	6	5
Urinary tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	1 / 41 (2.44%)
occurrences (all)	1	0	1
Varicella	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 16 (6.25%)	0 / 14 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Naive_6062		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 48 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumor benign	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Ear tube insertion	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Induration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Injection site erythema	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	46 / 48 (95.83%)		
occurrences (all)	92		
Injection site induration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	28 / 48 (58.33%)		
occurrences (all)	42		
Pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Swelling	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		

Injection site pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	46 / 48 (95.83%)		
occurrences (all)	94		
Injection site swelling	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	32 / 48 (66.67%)		
occurrences (all)	45		
Pyrexia	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	10 / 48 (20.83%)		
occurrences (all)	11		
Respiratory, thoracic and mediastinal disorders			
Asthma	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Cough	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Respiratory disorder	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Irritability	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	29 / 48 (60.42%)		
occurrences (all)	43		
Eating disorder	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	15 / 48 (31.25%)		
occurrences (all)	22		
Injury, poisoning and procedural complications			
Skin Abrasion (Excoriation)	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Laceration	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	13 / 48 (27.08%)		
occurrences (all)	17		
Somnolence	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	26 / 48 (54.17%)		
occurrences (all)	36		
Blood and lymphatic system disorders			
Lymphadenopathy	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			

Ear pain	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain upper	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences (all)	1		
Gastritis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Diarrhoea	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	4 / 48 (8.33%)		
occurrences (all)	5		
Vomiting	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	7 / 48 (14.58%)		
occurrences (all)	8		
Skin and subcutaneous tissue disorders			
Erythema	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Rash macular	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		

Rash	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	5 / 48 (10.42%)		
occurrences (all)	8		
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	24 / 48 (50.00%)		
occurrences (all)	32		
Infections and infestations			
Conjunctivitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Ear infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 48 (2.08%)		
occurrences (all)	1		
Rhinitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 48 (4.17%)		
occurrences (all)	2		
Tonsillitis	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Urinary tract infection	Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1 for all the reported events.		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		
Varicella	Additional description: Additional description: Subject affected number for the reporting group 4rMenB, 4rMenB+OMV, Naive_4042, Naive_6062 were generated through MedDRA version 15 and the corresponding AE occurences all number were generated using MedDRA version 17.1		
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 48 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Not specified

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/24722351

http://www.ncbi.nlm.nih.gov/pubmed/23958808