Clinical trial results:
Phase IV, open-label, randomized study to enrol healthy adult volunteers, naïve to any previous meningococcal vaccination or meningococcal disease, aged 18-50 years, to be either vaccinated with GSK MenACWY vaccine (Menveo) or GSK rMenB+OMV NZ vaccine (Bexsero), and serve as donors of human blood for conversion into serum to use in the development, qualification, validation and maintenance of immunological assays and to support preclinical research activities, clinical development and life cycle management of GSK Biologicals vaccines

Summary

EudraCT number	2017-002919-33
Trial protocol	DE
Global end of trial date	22 June 2022

Results information

Result version number	v1
This version publication date	11 June 2023
First version publication date	11 June 2023

Trial information

Trial identification

Sponsor protocol code	207911

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut, 89, Rixensart, Belgium, 1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	28 September 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 May 2022
Global end of trial reached?	Yes
Global end of trial date	22 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To collect baseline (Visit 1, Visit 2 or Visit 3, depending on the study group) and post vaccination (Visits 5, 8; Visits 5, 9; Visits 6, 9 or Visits 7, 9, depending on the study group) blood sample donations to serve for the development, qualification, validation and maintenance of immunological assays and to support the preclinical research activities, clinical development and life cycle management of GSK Biologicals' vaccines.

Protection of trial subjects:

Blood samples were obtained by trained professionals, and medical assistance was readily available. Blood was collected only from eligible subjects who did not present any reason for deferring the blood draw. All subjects were supervised for 30 minutes after vaccination, with appropriate medical treatment readily available. Vaccines were administered according to their marketing indication and SmPC (summary of product characteristics) only to eligible subjects who had no contraindications to any components of the vaccines/products.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 March 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 463
Country: Number of subjects enrolled	Germany: 558
Worldwide total number of subjects	1021
EEA total number of subjects	558

Notes:

Subjects enrolled per age group

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

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	1021
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

To adhere to local health guidelines (Australian Red Cross, 2016), 3 MenACWY groups were formed to ensure minimum 90-day interval between blood drawn at Days -83, -60, -30, 31, 61, and 151. The rMenB+OMV NZ group was not split due to sufficient intervals between post-vaccination blood sampling points (Day 8 and Day 98).

Pre-assignment

Screening details:

Out of 1021 participants enrolled, 60 participants did not receive vaccination as they did not meet the eligibility criteria or withdrew from the study, therefore only 961 participants were included in the Exposed Set and started the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	rMenB+OMV NZ Group

Arm description:

Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98.

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:

Two doses of rMenB+OMV NZ vaccine at Day 1 and Day 61

Arm title	MenACWY 1 Group

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.

Arm type	Experimental
Investigational medicinal product name	MenACWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Effervescent powder, Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

Arm title	MenACWY 2 Group

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.

Arm type	Experimental

Investigational medicinal product name	MenACWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Effervescent powder, Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

Arm title	MenACWY 3 Group

Arm description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.

Arm type	Experimental
Investigational medicinal product name	MenACWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Effervescent powder, Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of MenACWY vaccine at Day 1

Number of subjects in period 1[1]	rMenB+OMV NZ Group	MenACWY 1 Group	MenACWY 2 Group
Started	470	165	165
Completed	454	161	163
Not completed	16	4	2
Consent withdrawn by subject	9	3	1
Adverse event, non-fatal	-	1	-
Other	2	-	1
Lost to follow-up	5	-	-

Number of subjects in period 1[1]	MenACWY 3 Group
Started	161
Completed	157
Not completed	4
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Other	-
Lost to follow-up	3

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of 1021 participants enrolled, 60 participants did not receive vaccination as they did not meet the eligibility criteria or withdrew from the study, therefore only 961 participants were included

in the Exposed Set and started the study.

Baseline characteristics

Reporting groups	
Reporting group title	rMenB+OMV NZ Group
Reporting group description:	
Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98.	
Reporting group title	MenACWY 1 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.	
Reporting group title	MenACWY 2 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.	
Reporting group title	MenACWY 3 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.	

Reporting group values	rMenB+OMV NZ Group	MenACWY 1 Group	MenACWY 2 Group
Number of subjects	470	165	165
Age Categorical Units: Participants			
Age continuous Units: years			
arithmetic mean	32.8	33.3	33.3
standard deviation	± 8.8	± 9.1	± 9.0
Sex: Female, Male Units: Participants			
Female	295	99	105
Male	175	66	60
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	29	13	15
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	430	150	149
More than one race	9	2	1
Unknown or Not Reported	2	0	0

Reporting group values	MenACWY 3 Group	Total	
Number of subjects	161	961	
Age Categorical Units: Participants			

Age continuous Units: years			
arithmetic mean	32.9		
standard deviation	± 8.8	-	
Sex: Female, Male Units: Participants			
Female	109	608	
Male	52	353	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	8	65	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	147	876	
More than one race	6	18	
Unknown or Not Reported	0	2	

End points

End points reporting groups

Reporting group title	rMenB+OMV NZ Group
Reporting group description:	
Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61 and blood samples were collected at Day -83, Day 8, and Day 98.	
Reporting group title	MenACWY 1 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -83, Day 8, and Day 151.	
Reporting group title	MenACWY 2 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -60, Day 31, and Day 151.	
Reporting group title	MenACWY 3 Group
Reporting group description:	
Participants vaccinated intramuscularly with Menveo vaccine at Day 1 and blood samples were collected at Day -30, Day 61, and Day 151.	

Primary: Number of human blood samples collected for conversion into serum at Day -83

End point title	Number of human blood samples collected for conversion into serum at Day -83[1][2]
End point description:	
The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -83, blood samples were collected only for rMenB+OMV NZ group and MenACWY 1 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.	
End point type	Primary
End point timeframe:	
At Day -83 [83 days before first vaccination (Day 1)]	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day -83, blood samples were collected only for the rMenB+OMV NZ and MenACWY 1 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	rMenB+OMV NZ Group	MenACWY 1 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	470	165		
Units: Blood samples				
Number of Blood Samples Analyzed	5578	1936		

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day 8

End point title	Number of human blood samples collected for conversion into serum at Day 8[3][4]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 8, blood samples were collected only for rMenB+OMV NZ group and MenACWY 1 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day 8

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day 8, blood samples were collected only for the rMenB+OMV NZ and MenACWY 1 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	rMenB+OMV NZ Group	MenACWY 1 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	462	162		
Units: Blood samples				
Number of Blood Samples Analyzed	5396	1907		

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day 98

End point title	Number of human blood samples collected for conversion into serum at Day 98[5][6]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities

and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 98, blood samples were collected only for rMenB+OMV NZ group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day 98

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: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day 98, blood samples were collected only for the rMenB+OMV NZ group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	rMenB+OMV NZ Group			
Subject group type	Reporting group			
Number of subjects analysed	454			
Units: Blood samples				
Number of Blood Samples Analyzed	5204			

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day 151

End point title	Number of human blood samples collected for conversion into serum at Day 151[7][8]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 151, blood samples were collected only for MenACWY 1, 2 and 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day 151

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day 151, blood samples were collected only for MenACWY 1, 2, and 3 groups. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	MenACWY 1 Group	MenACWY 2 Group	MenACWY 3 Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	161	162	156	
Units: Blood samples				
Number of Blood Samples Analyzed	1869	1866	1752	

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day -60

End point title	Number of human blood samples collected for conversion into serum at Day -60[9][10]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -60, blood samples were collected only for MenACWY 2 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day -60 [60 days before first vaccination (Day 1)]

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day -60, blood samples were collected only for the MenACWY 2 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	MenACWY 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: Blood samples				
Number of Blood Samples Analyzed	1957			

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day-30

End point title	Number of human blood samples collected for conversion into serum at Day-30[11][12]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day -30, blood samples were collected only for MenACWY 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day -30 [30 days before first vaccination (Day 1)]

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day -30, blood samples were collected only for the MenACWY 3 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	MenACWY 3 Group			
Subject group type	Reporting group			
Number of subjects analysed	161			
Units: Blood samples				
Number of Blood Samples Analyzed	1894			

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day 31

End point title	Number of human blood samples collected for conversion into serum at Day 31[13][14]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 31, blood samples were collected only for MenACWY 2 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day 31

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day 31, blood samples were collected only for the MenACWY 2 group. The participants

included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	MenACWY 2 Group			
Subject group type	Reporting group			
Number of subjects analysed	163			
Units: Blood samples				
Number of Blood Samples Analyzed	1920			

Statistical analyses

No statistical analyses for this end point

Primary: Number of human blood samples collected for conversion into serum at Day 61

End point title	Number of human blood samples collected for conversion into serum at Day 61[15][16]

End point description:

The Serum Bactericidal Assay (SBA) using human serum used to measure the induction of functional bactericidal antibodies directed against Neisseria meningitidis. To comply with local health authorities and guidelines [Australian Red Cross, 2016], blood samples were collected with the minimum interval of approximately 90 days. At Day 61, blood samples were collected only for MenACWY 3 group. Analysis was performed on blood samples collected from exposed set, which included all participants in the enrolled set who received a study vaccination. The participants included in this outcome measure are based on the data collected at specific blood sampling timepoints.

End point type	Primary

End point timeframe:

At Day 61

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: On Day 61, blood samples were collected only for the MenACWY 3 group. The participants included in this outcome measure are based on the data collected at specific blood sampling time points.

End point values	MenACWY 3 Group			
Subject group type	Reporting group			
Number of subjects analysed	159			
Units: Blood samples				
Number of Blood Samples Analyzed	1809			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with atleast one Serious Adverse Events (SAEs) related to vaccination

End point title	Number of participants with atleast one Serious Adverse Events (SAEs) related to vaccination

End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, results in disability/incapacity in a subject or is a congenital anomaly/ birth defect in the offspring of a study subject. AE(s) considered as SAE(s) also include invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that do not result in hospitalization, as per the medical or scientific judgement of the physician. Related=AE assessed by the investigator as related to the vaccination. Analysis was performed on blood samples collected from exposed set, which included all participants subjects in the exposed set who provide safety data.

End point type	Secondary

End point timeframe:

Throughout the study period (approximately 4 years)

End point values	rMenB+OMV NZ Group	MenACWY 1 Group	MenACWY 2 Group	MenACWY 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	470	165	165	161
Units: Participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Serious Adverse Events (SAEs) were collected throughout the study period (Upto 4 years)

Adverse event reporting additional description:

According to the pre-specified protocol, only serious adverse events and pregnancy-related events were to be collected. As no pregnancies have been reported in this study, the total number of participants at risk and affected by any other adverse events is zero.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	rMenB+OMV NZ Group

Reporting group description:

Participants vaccinated intramuscularly with Bexsero vaccine at Day 1 and Day 61.

Reporting group title	MenACWY 3 Group

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

Reporting group title	MenACWY 2 Group

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

Reporting group title	MenACWY 1 Group

Reporting group description:

Participants vaccinated intramuscularly with Menveo vaccine at Day 1.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: According to the pre-specified protocol, only serious adverse events and pregnancy-related events were to be collected. As no pregnancies have been reported in this study, the total number of participants at risk and affected by any other adverse events is zero.

Serious adverse events	rMenB+OMV NZ Group	MenACWY 3 Group	MenACWY 2 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 470 (0.64%)	0 / 161 (0.00%)	1 / 165 (0.61%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 470 (0.00%)	0 / 161 (0.00%)	1 / 165 (0.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Immune thrombocytopenia			

subjects affected / exposed	0 / 470 (0.00%)	0 / 161 (0.00%)	0 / 165 (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
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	1 / 470 (0.21%)	0 / 161 (0.00%)	0 / 165 (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
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	1 / 470 (0.21%)	0 / 161 (0.00%)	0 / 165 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 470 (0.21%)	0 / 161 (0.00%)	0 / 165 (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

Serious adverse events	MenACWY 1 Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 165 (0.61%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 165 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Immune thrombocytopenia			
subjects affected / exposed	1 / 165 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Inguinal hernia			
subjects affected / exposed	0 / 165 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Adnexal torsion			
subjects affected / exposed	0 / 165 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 165 (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: 0 %

Non-serious adverse events	rMenB+OMV NZ Group	MenACWY 3 Group	MenACWY 2 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 470 (0.00%)	0 / 161 (0.00%)	0 / 165 (0.00%)

Non-serious adverse events	MenACWY 1 Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 165 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 September 2017	Detailed title, Primary Objective was reworded. Duration of the study for individual subjects was updated. Minor edits and wordings update have been made.
19 January 2018	Discrepancies have been noted in Study Design Overview and Intervals between study visits Table. Further, day number for Visits 5 to 9 needed to reflect in the following way: Visit 5: Day 8, Visit 6: Day 31, Visit 7: Day 61, Visit 8: 98 and Visit 9: 151.
13 September 2019	To clarify the minimum interval between first (blood draw) study visit and next (vaccination) study visit for all study groups
28 April 2020	The purpose of the amendment is to protect participant's welfare, and as far as possible ensure the potential benefit to the participant and promote data integrity.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported