Clinical trial results:
A descriptive, Phase IV, open-label, single-arm multi-center study to assess the immunogenicity and safety of MenQuadfi® as a booster vaccine in healthy toddlers 12 to 23 months of age who had been primed with at least 1 dose of another quadrivalent meningococcal conjugate vaccine, ie, Nimenrix® (MCV4-TT) or Menveo® (MCV4-CRM), in infancy

Summary

EudraCT number	2025-000002-42
Trial protocol	Outside EU/EEA
Global end of trial date	09 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	MEQ00086

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05929651
WHO universal trial number (UTN)	U1111-1277-6838

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	14 Espace Henry Vallée, Lyon, France, 69007
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.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	04 March 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the immune response to a booster dose of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid (MenACYW) conjugate vaccine as measured by serum bactericidal assay using human complement (hSBA) in toddlers aged 12 to 23 months, who had been primed with at least 1 dose of another quadrivalent meningococcal conjugate vaccine (MCV4) vaccine during infancy; antibody response as measured by hSBA and serum bactericidal antibody assay using baby rabbit complement (rSBA) in toddlers 12 to 23 months of age who had been primed with at least 1 dose, 2 doses and 1 dose of another MCV4 vaccine during infancy; and antibody responses to tetanus toxoid in toddlers 12 to 23 months of age who had been primed with at least 1 dose of another MCV4 vaccine during infancy.

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available onsite in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 September 2023
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	Argentina: 71
Worldwide total number of subjects	71
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	71
Children (2-11 years)	0
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:

This study was conducted at 2 investigational sites in Argentina between 07 September 2023 to 09 September 2024.

Pre-assignment

Screening details:

A total of 71 participants were enrolled in this study.

Period 1

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

Arms

Arm title	MenACYW conjugate vaccine

Arm description:

Participants who had received at least 1 of 2 priming doses of either Nimenrix® or Menveo® vaccine during infancy as part of their routine immunization before 12 months of age received a single booster dose (0.5 milliliter [mL]) of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid (MenACYW conjugate vaccine) as an intramuscular (IM) injection at Day 1.

Arm type	Experimental
Investigational medicinal product name	MenACYW conjugate vaccine
Investigational medicinal product code	
Other name	Meningococcal Polysaccharide (Serogroups A, C, W, and Y) Tetanus Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

A 0.5 mL dose was administered as an IM injection at Day 1.

Number of subjects in period 1	MenACYW conjugate vaccine
Started	71
Safety analysis set (SafAS)	69
Completed	68
Not completed	3
Protocol Deviation	1
Withdrawal by parents/acceptable representatives	2

Baseline characteristics

Reporting groups	
Reporting group title	MenACYW conjugate vaccine
Reporting group description:	
Participants who had received at least 1 of 2 priming doses of either Nimenrix® or Menveo® vaccine during infancy as part of their routine immunization before 12 months of age received a single booster dose (0.5 milliliter [mL]) of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid (MenACYW conjugate vaccine) as an intramuscular (IM) injection at Day 1.	

Reporting group values	MenACYW conjugate vaccine	Total	
Number of subjects	71	71	
Age categorical Units: Subjects			
Age Continuous Units: months			
arithmetic mean	14.3		
standard deviation	± 1.50	-	
Sex: Female, Male Units: Participants			
Female	34	34	
Male	37	37	
Race and Ethnicity Not Collected Units: Subjects			
Not collected	71	71	

End points

End points reporting groups

Reporting group title	MenACYW conjugate vaccine

Reporting group description:

Participants who had received at least 1 of 2 priming doses of either Nimenrix® or Menveo® vaccine during infancy as part of their routine immunization before 12 months of age received a single booster dose (0.5 milliliter [mL]) of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid (MenACYW conjugate vaccine) as an intramuscular (IM) injection at Day 1.

Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:8 Against Meningococcal Serogroups A, C, Y, and W[1]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using human complement (hSBA). Percentages are rounded to the nearest tenth. The per-protocol analysis set (PPAS) was a subset of the full analysis set (FAS). The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n= 61)	72.1 (59.2 to 82.9)			
Serogroup A: Day 31 (n= 58)	100 (93.8 to 100)			
Serogroup C: Day 1 (n= 63)	60.3 (47.2 to 72.4)			
Serogroup C: Day 31 (n= 61)	100 (94.1 to 100)			
Serogroup Y: Day 1 (n= 62)	67.7 (54.7 to 79.1)			
Serogroup Y: Day 31 (n= 52)	100 (93.2 to 100)			
Serogroup W: Day 1 (n= 64)	73.4 (60.9 to 83.7)			
Serogroup W: Day 31 (n= 58)	100 (93.8 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, Y, and W as Measured by Serum Bactericidal Assay Using Human Complement

End point title	Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, Y, and W as Measured by Serum Bactericidal Assay Using Human Complement[2]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using human complement (hSBA). The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

[2] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=61)	14.0 (10.1 to 19.4)			
Serogroup A: Day 31 (n=58)	244 (163 to 366)			
Serogroup C: Day 1 (n=63)	12.3 (8.29 to 18.2)			
Serogroup C: Day 31 (n=61)	1072 (805 to 1426)			
Serogroup Y: Day 1 (n=62)	14.0 (9.70 to 20.2)			
Serogroup Y: Day 31 (n=52)	945 (683 to 1309)			
Serogroup W: Day 1 (n=64)	16.9 (11.8 to 24.2)			
Serogroup W: Day 31 (n=58)	953 (712 to 1275)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 Against Meningococcal Serogroups A, C, Y, and W[3]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using human complement (hSBA). Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n= 61)	96.7 (88.7 to 99.6)			
Serogroup A: Day 31 (n= 58)	100 (93.8 to 100)			
Serogroup C: Day 1 (n= 63)	76.2 (63.8 to 86.0)			
Serogroup C: Day 31 (n= 61)	100 (94.1 to 100)			
Serogroup Y: Day 1 (n= 62)	85.5 (74.2 to 93.1)			
Serogroup Y: Day 31 (n= 52)	100 (93.2 to 100)			
Serogroup W: Day 1 (n= 64)	87.5 (76.8 to 94.4)			
Serogroup W: Day 31 (n= 58)	100 (93.8 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=4-Fold Rise From Pre-vaccination to Post-Vaccination

End point title	Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=4-Fold Rise From Pre-

	vaccination to Post-Vaccination[4]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using human complement (hSBA). Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

[4] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=56)	91.1 (80.4 to 97.0)			
Serogroup C (n=59)	100 (93.9 to 100)			
Serogroup Y (n=51)	96.1 (86.5 to 99.5)			
Serogroup W (n=57)	100 (93.7 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Human Complement

End point title	Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Human Complement[5]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using human complement (hSBA). hSBA vaccine seroresponse was defined for a participant with a pre-vaccination titer <1:8 as a post-vaccination titer of >=1:16 and for a participant with a pre-vaccination titer >=1:8 as a post-vaccination titer that is at least 4-fold greater than the pre-vaccination titer. Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post vaccination on Day 1)

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	59			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=56)	91.1 (80.4 to 97.0)			
Serogroup C (n=59)	100 (93.9 to 100)			
Serogroup Y (n=51)	96.1 (86.5 to 99.5)			
Serogroup W (n=57)	100 (93.7 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers Against Meningococcal Serogroups A, C, Y, and W as Measured by Serum Bactericidal Antibody Assay Using Baby Rabbit Complement

End point title	Geometric Mean Titers Against Meningococcal Serogroups A, C, Y, and W as Measured by Serum Bactericidal Antibody Assay Using Baby Rabbit Complement[6]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using baby rabbit complement (rSBA). The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

[6] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=55)	82.3 (33.3 to 203)			
Serogroup A: Day 31 (n=64)	4715 (3547 to 6268)			
Serogroup C: Day 1 (n=61)	11.6 (6.54 to 20.7)			
Serogroup C: Day 31 (n=64)	3676 (2707 to 4990)			
Serogroup Y: Day 1 (n=59)	30.9 (15.6 to 61.2)			

Serogroup Y: Day 31 (n=64)	5198 (4091 to 6604)			
Serogroup W: Day 1 (n=63)	28.0 (14.7 to 53.5)			
Serogroup W: Day 31 (n=64)	9329 (6627 to 13132)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Antibody Assay Using Baby Rabbit Complement Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W

End point title	Percentage of Participants With Serum Bactericidal Antibody Assay Using Baby Rabbit Complement Antibody Titers >=1:8 and >=1:128 Against Meningococcal Serogroups A, C, Y, and W[7]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using baby rabbit complement (rSBA). Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A: >=1:8: Day 1 (n=55)	56.4 (42.3 to 69.7)			
Serogroup A: >=1:128: Day 1 (n=55)	54.5 (40.6 to 68.0)			
Serogroup A: >=1:8: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup A: >=1:128: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup C: >=1:8: Day 1 (n=61)	39.3 (27.1 to 52.7)			
Serogroup C: >=1:128: Day 1 (n=61)	24.6 (14.5 to 37.3)			
Serogroup C: >=1:8: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup C: >=1:128: Day 31 (n=64)	100 (94.4 to 100)			

Serogroup Y: >=1:8: Day 1 (n=59)	55.9 (42.4 to 68.8)			
Serogroup Y: >=1:128: Day 1 (n=59)	44.1 (31.2 to 57.6)			
Serogroup Y: >=1:8: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup Y: >=1:128: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup W: >=1:8: Day 1 (n=63)	61.9 (48.8 to 73.9)			
Serogroup W: >=1:128: Day 1 (n=63)	41.3 (29.0 to 54.4)			
Serogroup W: >=1:8: Day 31 (n=64)	100 (94.4 to 100)			
Serogroup W: >=1:128: Day 31 (n=64)	100 (94.4 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Antibody Assay Using Baby Rabbit Complement Antibody Titers >=4-Fold Rise From Pre-vaccination to Post-Vaccination

End point title	Percentage of Participants With Serum Bactericidal Antibody Assay Using Baby Rabbit Complement Antibody Titers >=4-Fold Rise From Pre-vaccination to Post-Vaccination[8]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using baby rabbit complement (rSBA). Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on Day 1)

Notes:

[8] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=54)	83.3 (70.7 to 92.1)			
Serogroup C (n=60)	98.3 (91.1 to 100)			
Serogroup Y (n=58)	98.3 (90.8 to 100)			
Serogroup W (n=62)	100 (94.2 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Antibody Assay Using Baby Rabbit Complement

End point title	Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Antibody Assay Using Baby Rabbit Complement[9]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured in a serum bactericidal assay using baby rabbit complement (rSBA). rSBA vaccine seroresponse was defined for a participant with a pre-vaccination titer <1:8 as a post-vaccination titer of >=1:32 and for a participant with a pre-vaccination titer >=1:8 as a post-vaccination titer that is at least 4-fold greater than the pre-vaccination titer. Percentages are rounded to the nearest tenth. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62			
Units: Percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=54)	83.3 (70.7 to 92.1)			
Serogroup C (n=60)	98.3 (91.1 to 100)			
Serogroup Y (n=58)	98.3 (90.8 to 100)			
Serogroup W (n=62)	100 (94.2 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Immediate Unsolicited Systemic Adverse Events (AEs)

End point title	Number of Participants With Immediate Unsolicited Systemic Adverse Events (AEs)[10]

End point description:

An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, i.e., pre-listed in the case report form (CRF) in terms of diagnosis and onset window post-vaccination. The SafAS included participants who received the study vaccine.

End point type	Primary

End point timeframe:

Up to 30 minutes post-vaccination on Day 1

Notes:

[10] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Concentrations (GMCs) of Antibodies Against Tetanus Toxoid

End point title	Geometric Mean Concentrations (GMCs) of Antibodies Against Tetanus Toxoid[11]

End point description:

Geometric Mean Concentrations (GMCs) of anti-tetanus toxoid antibodies was measured by diphtheria, tetanus, pertussis multiplexed electrochemiluminescent assay. The PPAS was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result. Here, n refers to the number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 1 (pre-vaccination) and Day 31 (30 days post-vaccination on 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	65			
Units: International units/milliliter				
geometric mean (confidence interval 95%)				
Day 1 (n=65)	0.642 (0.482 to 0.854)			
Day 31 (n=64)	8.56 (6.17 to 11.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Adverse Events

End point title	Number of Participants With Unsolicited Adverse Events[12]

End point description:

An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, i.e., pre-listed in the CRF in terms of diagnosis and/or onset window post-vaccination. The SafAS included participants who received the study vaccine.

End point type	Primary

End point timeframe:

Up to 30 days post-vaccination on Day 1

Notes:

[12] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Participants	23			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Injection Site Reactions and Systemic Reactions

End point title	Number of Participants With Solicited Injection Site Reactions and Systemic Reactions[13]

End point description:

A solicited reaction was an "expected" adverse reaction (AR) (sign or symptom) observed and reported under the conditions (nature and onset) pre-listed in the protocol and CRF. An injection site reaction was an AR at and around the injection site. Solicited injection site reactions included injection site tenderness, injection site erythema and injection site swelling. Solicited systemic reactions included fever, vomiting, crying abnormal, drowsiness, appetite loss and irritability. The SafAS included participants who received the study vaccine.

End point type	Primary

End point timeframe:

Up to 7 days post-vaccination on Day 1

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Participants				
Solicited injection site reaction	24			
Solicited systemic reaction	35			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)

End point title	Number of Participants With Serious Adverse Events (SAEs) and Adverse Events of Special Interest (AESIs)[14]

End point description:

An SAE was any AE that at any dose resulted in death, was life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/birth defect, or was an important medical event. An AESI (serious or non-serious) was defined as one of scientific and medical concern specific to the Sponsor's study intervention or program, for which ongoing monitoring and rapid communication by the investigator to the Sponsor could be appropriate. The SafAS included participants who received the study vaccine.

End point type	Primary

End point timeframe:

From vaccination (Day 1) up to 30 days post vaccination, 31 days

Notes:

[14] - 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: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	MenACYW conjugate vaccine			
Subject group type	Reporting group			
Number of subjects analysed	69			
Units: Participants				
SAEs	1			
AESIs	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs, SAEs and all-cause mortality (deaths) were collected from vaccination (Day 1) up to 30 days post vaccination, 31 days

Adverse event reporting additional description:

Analysis was performed on SafAS.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	28.0

Reporting groups

Reporting group title	MenACYW conjugate vaccine

Reporting group description:

Participants who had received at least 1 of 2 priming doses of either Nimenrix® or Menveo® vaccine during infancy as part of their routine immunization before 12 months of age received a single booster dose (0.5 mL) of MenACYW conjugate vaccine as an IM injection at Day 1.

Serious adverse events	MenACYW conjugate vaccine		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 69 (1.45%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	1 / 69 (1.45%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	MenACYW conjugate vaccine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 69 (65.22%)		
Nervous system disorders			
Somnolence			
subjects affected / exposed	13 / 69 (18.84%)		
occurrences (all)	13		
General disorders and administration			

site conditions Injection Site Erythema subjects affected / exposed occurrences (all) Injection Site Pain subjects affected / exposed occurrences (all) Injection Site Swelling subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) Crying subjects affected / exposed occurrences (all)	 4 / 69 (5.80%) 4 21 / 69 (30.43%) 21 4 / 69 (5.80%) 4 14 / 69 (20.29%) 15 14 / 69 (20.29%) 14		
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	 13 / 69 (18.84%) 13 5 / 69 (7.25%) 5		
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	 22 / 69 (31.88%) 22		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	 4 / 69 (5.80%) 4		
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	 14 / 69 (20.29%) 14		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported