Clinical trial results:
Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adults, Adolescents, and Children in India and Healthy Adolescents and Children in the Republic of South Africa

Summary

EudraCT number	2020-004341-36
Trial protocol	Outside EU/EEA
Global end of trial date	28 January 2023

Results information

Result version number	v1 (current)
This version publication date	09 February 2025
First version publication date	09 February 2025

Trial information

Trial identification

Sponsor protocol code	MET55

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04143061
WHO universal trial number (UTN)	U1111-1183-6581

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	Discovery Drive, Swiftwater, PA, United States, 18370-0187
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 January 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of immunogenicity of a single dose of meningococcal polysaccharide (serogroups A, C, Y, and W) tetanus toxoid conjugate vaccine [MenACYW conjugate vaccine] compared to meningococcal (groups A, C, Y and W-135) polysaccharide diphtheria toxoid conjugate vaccine [Menactra®] in adolescents and children aged 2 to 17 years in terms of serum bactericidal assay using human complement (hSBA) titers.

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 on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 December 2019
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	India: 863
Country: Number of subjects enrolled	South Africa: 465
Worldwide total number of subjects	1328
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	626
Adolescents (12-17 years)	304
Adults (18-64 years)	356

From 65 to 84 years	41
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 17 investigational sites: 10 centers in India and 7 centers in the Republic of South Africa (RSA) between 30 December 2019 and 28 January 2023.

Pre-assignment

Screening details:

A total of 1328 participants were enrolled and randomized in the study. Toddlers were not enrolled in this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenACYW Conjugate Vaccine

Arm description:

Adult participants aged 18 to 55 years in India received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 0.

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

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 2: Menactra®

Arm description:

Adult participants aged 18 to 55 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Arm type	Active comparator
Investigational medicinal product name	Menactra®
Investigational medicinal product code	
Other name	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received Menactra® 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 3: MenACYW Conjugate Vaccine

Arm description:

Adult participants aged ≥56 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

Arm type	Experimental

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

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine

Arm description:

Adult participants aged ≥56 years in India received a single dose of 0.5 mL meningococcal polysaccharide vaccine (group A, C, Y and W135) [Quadri Meningo™] or any locally available licensed meningococcal vaccine as an IM injection on Day 0.

Arm type	Active comparator
Investigational medicinal product name	Quadri Meningo™
Investigational medicinal product code	
Other name	Meningococcal Polysaccharide Vaccine (Group A, C, Y & W135)
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received Quadri Meningo™ or any locally available licensed meningococcal vaccine 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 5: MenACYW Conjugate Vaccine

Arm description:

Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

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

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 6: Menactra®

Arm description:

Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Arm type	Active comparator
Investigational medicinal product name	Menactra®
Investigational medicinal product code	
Other name	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received Menactra® 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 7: MenACYW Conjugate Vaccine

Arm description:

Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

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

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection into the deltoid muscle of the arm.

Arm title	Group 8: Menactra®

Arm description:

Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Arm type	Active comparator
Investigational medicinal product name	Menactra®
Investigational medicinal product code	
Other name	Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received Menactra® 0.5 mL IM injection into the deltoid muscle of the arm.

Number of subjects in period 1	Group 1: MenACYW Conjugate Vaccine	Group 2: Menactra®	Group 3: MenACYW Conjugate Vaccine
Started	98	100	100
Completed	96	100	100
Not completed	2	0	0
Consent withdrawn by subject	2	-	-
Protocol Deviation	-	-	-
Withdrawal by Parent/Guardian	-	-	-

Number of subjects in period 1	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®
Started	100	232	233
Completed	100	224	229
Not completed	0	8	4
Consent withdrawn by subject	-	-	1
Protocol Deviation	-	-	-
Withdrawal by Parent/Guardian	-	8	3

Number of subjects in period 1	Group 7: MenACYW Conjugate Vaccine	Group 8: Menactra®
Started	233	232
Completed	226	220
Not completed	7	12

Consent withdrawn by subject	-	-
Protocol Deviation	5	5
Withdrawal by Parent/Guardian	2	7

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenACYW Conjugate Vaccine
Reporting group description:	
Adult participants aged 18 to 55 years in India received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 0.	
Reporting group title	Group 2: Menactra®
Reporting group description:	
Adult participants aged 18 to 55 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	
Reporting group title	Group 3: MenACYW Conjugate Vaccine
Reporting group description:	
Adult participants aged ≥56 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine
Reporting group description:	
Adult participants aged ≥56 years in India received a single dose of 0.5 mL meningococcal polysaccharide vaccine (group A, C, Y and W135) [Quadri Meningo™] or any locally available licensed meningococcal vaccine as an IM injection on Day 0.	
Reporting group title	Group 5: MenACYW Conjugate Vaccine
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 6: Menactra®
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	
Reporting group title	Group 7: MenACYW Conjugate Vaccine
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 8: Menactra®
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	

Reporting group values	Group 1: MenACYW Conjugate Vaccine	Group 2: Menactra®	Group 3: MenACYW Conjugate Vaccine
Number of subjects	98	100	100
Age categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	36.7	34.8	61.7
standard deviation	± 9.21	± 9.05	± 6.09
Sex: Female, Male Units: participants			
Female	30	31	24
Male	68	69	76

Race/Ethnicity, Customized Units: Subjects			
Asian	98	100	100
Black or African American	0	0	0
White	0	0	0
Not Reported	0	0	0
Unknown	0	0	0
Mixed Origin	0	0	0

Reporting group values	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®
Number of subjects	100	232	233
Age categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	61.1	9.39	9.34
standard deviation	± 5.61	± 4.19	± 4.10
Sex: Female, Male Units: participants			
Female	31	101	118
Male	69	131	115
Race/Ethnicity, Customized Units: Subjects			
Asian	100	232	233
Black or African American	0	0	0
White	0	0	0
Not Reported	0	0	0
Unknown	0	0	0
Mixed Origin	0	0	0

Reporting group values	Group 7: MenACYW Conjugate Vaccine	Group 8: Menactra®	Total
Number of subjects	233	232	1328
Age categorical Units: participants			
Age Continuous Units: years			
arithmetic mean	9.45	9.19	
standard deviation	± 4.01	± 4.19	-
Sex: Female, Male Units: participants			
Female	123	110	568
Male	110	122	760
Race/Ethnicity, Customized Units: Subjects			
Asian	0	0	863
Black or African American	142	139	281

White	9	10	19
Not Reported	6	3	9
Unknown	6	9	15
Mixed Origin	70	71	141

End points

End points reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine
Reporting group description:	
Adult participants aged 18 to 55 years in India received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 0.	
Reporting group title	Group 2: Menactra®
Reporting group description:	
Adult participants aged 18 to 55 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	
Reporting group title	Group 3: MenACYW Conjugate Vaccine
Reporting group description:	
Adult participants aged ≥56 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine
Reporting group description:	
Adult participants aged ≥56 years in India received a single dose of 0.5 mL meningococcal polysaccharide vaccine (group A, C, Y and W135) [Quadri Meningo™] or any locally available licensed meningococcal vaccine as an IM injection on Day 0.	
Reporting group title	Group 5: MenACYW Conjugate Vaccine
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 6: Menactra®
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	
Reporting group title	Group 7: MenACYW Conjugate Vaccine
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Reporting group title	Group 8: Menactra®
Reporting group description:	
Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	
Subject analysis set title	Group 5 + Group 7: MenACYW Conjugate Vaccine
Subject analysis set type	Per protocol
Subject analysis set description:	
Children and adolescent participants aged 2 to 17 years in India and RSA received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.	
Subject analysis set title	Group 6 + Group 8: Menactra®
Subject analysis set type	Per protocol
Subject analysis set description:	
Children and adolescent participants aged 2 to 17 years in India and RSA received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.	

Primary: Group 5 + 7 and Group 6 + 8: Percentage of Participants who Achieved Antibody Titers ≥1:8 Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 5 + 7 and Group 6 + 8: Percentage of Participants who Achieved Antibody Titers ≥1:8 Against Meningococcal Serogroups A, C, Y, and W
End point description:	
Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA.	

Percentages are rounded off to the tenth decimal place. As pre-specified in protocol, the endpoint was assessed in children and adolescents aged 2 to 17 years in India and RSA as combined groups: Group 5 + Group 7 and Group 6 + Group 8 as they received the same dose of MenACYW conjugate vaccine and Menactra® respectively. Analysis was performed on the per-protocol analysis set (PPAS) which was a subset of the full analysis set (FAS). The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

End point type	Primary

End point timeframe:

Day 30 (30 days post-vaccination on Day 0)

End point values	Group 5 + Group 7: MenACYW Conjugate Vaccine	Group 6 + Group 8: Menactra®		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	445	445		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=443, 443)	89.6 (86.4 to 92.3)	83.1 (79.2 to 86.4)		
Serogroup C (n=445, 443)	99.3 (98.0 to 99.9)	77.7 (73.5 to 81.4)		
Serogroup Y (n=445, 443)	96.6 (94.5 to 98.1)	85.6 (81.9 to 88.7)		
Serogroup W (n=445, 445)	98.7 (97.1 to 99.5)	87.6 (84.2 to 90.6)		

Statistical analyses

Statistical analysis title	Statistical analysis for Serogroup A

Statistical analysis description:

The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% confidence interval (CI) was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson Score method without continuity correction.

Comparison groups	Group 5 + Group 7: MenACYW Conjugate Vaccine v Group 6 + Group 8: Menactra®
Number of subjects included in analysis	890
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	6.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.03
upper limit	11.08

Statistical analysis title	Statistical analysis for Serogroup W

Statistical analysis description:

The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson Score method without continuity correction.

Comparison groups	Group 5 + Group 7: MenACYW Conjugate Vaccine v Group 6 + Group 8: Menactra®
Number of subjects included in analysis	890
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	11.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.86
upper limit	14.47

Statistical analysis title	Statistical analysis for Serogroup Y

Statistical analysis description:

The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson Score method without continuity correction.

Comparison groups	Group 5 + Group 7: MenACYW Conjugate Vaccine v Group 6 + Group 8: Menactra®
Number of subjects included in analysis	890
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	11.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.43
upper limit	14.89

Statistical analysis title	Statistical analysis for Serogroup C

Statistical analysis description:

The overall non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was >-10% for all 4 serogroups. 95% CI of the difference was calculated from the Wilson Score method without continuity correction.

Comparison groups	Group 5 + Group 7: MenACYW Conjugate Vaccine v Group 6 + Group 8: Menactra®

Number of subjects included in analysis	890
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Difference in percentage of participants
Point estimate	21.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.82
upper limit	25.8

Secondary: Group 1 and Group 2: Geometric Mean Titers (GMTs) of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 1 and Group 2: Geometric Mean Titers (GMTs) of Antibodies Against Meningococcal Serogroups A, C, Y, and W[1]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and serum bactericidal assay using baby rabbit complement (rSBA). Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[1] - 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: Only participants in Group 1 and Group 2 of the study were analyzed in this endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine	Group 2: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	99		
Units: titer				
geometric mean (confidence interval 95%)				
hSBA: Serogroup A: Day 0 (n=95,99)	7.28 (6.03 to 8.78)	9.60 (7.68 to 12.0)		
hSBA: Serogroup A: Day 30 (n=94,99)	52.8 (34.7 to 80.3)	39.2 (27.8 to 55.3)		
hSBA: Serogroup C: Day 0 (n=95,99)	6.20 (4.99 to 7.70)	7.05 (5.53 to 8.99)		
hSBA: Serogroup C: Day 30 (n=95,99)	551 (365 to 831)	107 (68.8 to 165)		
hSBA: Serogroup Y: Day 0 (n=95,99)	5.24 (3.86 to 7.11)	4.03 (3.09 to 5.25)		
hSBA: Serogroup Y: Day 30 (n=95,99)	119 (80.2 to 177)	47.4 (30.7 to 73.1)		
hSBA: Serogroup W: Day 0 (n=95,99)	4.18 (3.39 to 5.15)	4.17 (3.39 to 5.14)		
hSBA: Serogroup W: Day 30 (n=94,99)	106 (72.8 to 153)	63.1 (44.7 to 89.1)		

rSBA: Serogroup A: Day 0 (n=45,47)	194 (81.3 to 463)	64.0 (25.9 to 158)		
rSBA: Serogroup A: Day 30 (n=45,48)	10644 (7745 to 14629)	4467 (3428 to 5820)		
rSBA: Serogroup C: Day 0 (n=45,49)	5.88 (3.51 to 9.86)	4.88 (3.00 to 7.93)		
rSBA: Serogroup C: Day 30 (n=45,48)	12227 (7923 to 18868)	1149 (612 to 2158)		
rSBA: Serogroup Y: Day 0 (n=44,43)	9.36 (4.33 to 20.2)	9.40 (4.12 to 21.5)		
rSBA: Serogroup Y: Day 30 (n=43,47)	5934 (3758 to 9372)	3534 (2545 to 4909)		
rSBA: Serogroup W: Day 0 (n=45,49)	15.5 (6.49 to 37.1)	7.56 (3.49 to 16.4)		
rSBA: Serogroup W: Day 30 (n=45,48)	16638 (10325 to 26812)	7732 (4098 to 14589)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 1 and Group 2: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 1 and Group 2: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W[2]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Percentages are rounded off to the tenth decimal place. Percentage of participants who achieved antibody titers ≥1:4 and ≥1:8 by hSBA and ≥1:8 and ≥1:128 by rSBA are reported. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[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: Only participants in Group 1 and Group 2 of the study were analyzed in this endpoint.

End point values	Group 1: MenACYW Conjugate Vaccine	Group 2: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	99		
Units: percentage of participants				
number (confidence interval 95%)				
hSBA: Serogroup A: Day 0: ≥1:4 (n=95,99)	81.1 (71.7 to 88.4)	87.9 (79.8 to 93.6)		
hSBA: Serogroup A: Day 0: ≥1:8 (n=95,99)	61.1 (50.5 to 70.9)	72.7 (62.9 to 81.2)		
hSBA: Serogroup A: Day 30: ≥1:4 (n=94,99)	87.2 (78.8 to 93.2)	93.9 (87.3 to 97.7)		

hSBA: Serogroup A: Day 30: ≥1:8 (n=94,99)	76.6 (66.7 to 84.7)	87.9 (79.8 to 93.6)		
hSBA: Serogroup C: Day 0: ≥1:4 (n=95,99)	69.5 (59.2 to 78.5)	69.7 (59.6 to 78.5)		
hSBA: Serogroup C: Day 0: ≥1:8 (n=95,99)	47.4 (37.0 to 57.9)	50.5 (40.3 to 60.7)		
hSBA: Serogroup C: Day 30: ≥1:4 (n=95,99)	98.9 (94.3 to 100)	93.9 (87.3 to 97.7)		
hSBA: Serogroup C: Day 30: ≥1:8 (n=95,99)	96.8 (91.0 to 99.3)	88.9 (81.0 to 94.3)		
hSBA: Serogroup Y: Day 0: ≥1:4 (n=95,99)	38.9 (29.1 to 49.5)	30.3 (21.5 to 40.4)		
hSBA: Serogroup Y: Day 0: ≥1:8 (n=95,99)	29.5 (20.6 to 39.7)	24.2 (16.2 to 33.9)		
hSBA: Serogroup Y: Day 30: ≥1:4 (n=95,99)	93.7 (86.8 to 97.6)	82.8 (73.9 to 89.7)		
hSBA: Serogroup Y: Day 30: ≥1:8 (n=95,99)	92.6 (85.4 to 97.0)	76.8 (67.2 to 84.7)		
hSBA: Serogroup W: Day 0: ≥1:4 (n=95,99)	44.2 (34.0 to 54.8)	44.4 (34.5 to 54.8)		
hSBA: Serogroup W: Day 0: ≥1:8 (n=95,99)	29.5 (20.6 to 39.7)	29.3 (20.6 to 39.3)		
hSBA: Serogroup W: Day 30: ≥1:4 (n=94,99)	96.8 (91.0 to 99.3)	96.0 (90.0 to 98.9)		
hSBA: Serogroup W: Day 30: ≥1:8 (n=94,99)	93.6 (86.6 to 97.6)	90.9 (83.4 to 95.8)		
rSBA: Serogroup A: Day 0: ≥1:8 (n=45,47)	75.6 (60.5 to 87.1)	61.7 (46.4 to 75.5)		
rSBA: Serogroup A: Day 0: ≥1:128 (n=45,47)	62.2 (46.5 to 76.2)	48.9 (34.1 to 63.9)		
rSBA: Serogroup A: Day 30: ≥1:8 (n=45,48)	100 (92.1 to 100)	100 (92.6 to 100)		
rSBA: Serogroup A: Day 30: ≥1:128 (n=45,48)	100 (92.1 to 100)	100 (92.6 to 100)		
rSBA: Serogroup C: Day 0: ≥1:8 (n=45,49)	28.9 (16.4 to 44.3)	24.5 (13.3 to 38.9)		
rSBA: Serogroup C: Day 0: ≥1:128 (n=45,49)	11.1 (3.7 to 24.1)	10.2 (3.4 to 22.2)		
rSBA: Serogroup C: Day 30: ≥1:8 (n=45,48)	100 (92.1 to 100)	95.8 (85.7 to 99.5)		
rSBA: Serogroup C: Day 30: ≥1:128 (n=45,48)	100 (92.1 to 100)	89.6 (77.3 to 96.5)		
rSBA: Serogroup Y: Day 0: ≥1:8 (n=44,43)	29.5 (16.8 to 45.2)	25.6 (13.5 to 41.2)		
rSBA: Serogroup Y: Day 0: ≥1:128 (n=44,43)	25.0 (13.2 to 40.3)	23.3 (11.8 to 38.6)		
rSBA: Serogroup Y: Day 30: ≥1:8 (n=43,47)	97.7 (87.7 to 99.9)	100 (92.5 to 100)		
rSBA: Serogroup Y: Day 30: ≥1:128 (n=43,47)	97.7 (87.7 to 99.9)	100 (92.5 to 100)		
rSBA: Serogroup W: Day 0: ≥1:8 (n=45,49)	35.6 (21.9 to 51.2)	20.4 (10.2 to 34.3)		
rSBA: Serogroup W: Day 0: ≥1:128 (n=45,49)	31.1 (18.2 to 46.6)	20.4 (10.2 to 34.3)		
rSBA: Serogroup W: Day 30: ≥1:8 (n=45,48)	100 (92.1 to 100)	97.9 (88.9 to 99.9)		
rSBA: Serogroup W: Day 30: ≥1:128 (n=45,48)	100 (92.1 to 100)	97.9 (88.9 to 99.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 3 and Group 4: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 3 and Group 4: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W[3]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[3] - 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: Only participants in Group 3 and Group 4 of the study were analyzed in this endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	96		
Units: titer				
geometric mean (confidence interval 95%)				
hSBA: Serogroup A: Day 0 (n=97,96)	15.3 (12.2 to 19.3)	12.5 (10.2 to 15.4)		
hSBA: Serogroup A: Day 30 (n=96,96)	56.6 (38.2 to 83.9)	36.2 (26.8 to 48.8)		
hSBA: Serogroup C: Day 0 (n=97,96)	8.00 (6.18 to 10.4)	8.00 (6.13 to 10.4)		
hSBA: Serogroup C: Day 30 (n=97,96)	393 (255 to 606)	159 (102 to 248)		
hSBA: Serogroup Y: Day 0 (n=97,96)	6.36 (4.57 to 8.86)	6.97 (5.03 to 9.68)		
hSBA: Serogroup Y: Day 30 (n=97,96)	197 (127 to 303)	55.4 (35.5 to 86.4)		
hSBA: Serogroup W: Day 0 (n=97,96)	4.42 (3.53 to 5.54)	5.66 (4.40 to 7.27)		
hSBA: Serogroup W: Day 30 (n=97,96)	90.8 (60.4 to 137)	34.6 (23.5 to 51.2)		
rSBA: Serogroup A: Day 0 (n=48,47)	83.0 (37.0 to 186)	46.3 (20.1 to 106)		
rSBA: Serogroup A: Day 30 (n=49,47)	5834 (3730 to 9124)	4677 (2935 to 7455)		
rSBA: Serogroup C: Day 0 (n=49,47)	6.47 (3.69 to 11.3)	5.53 (3.06 to 9.99)		
rSBA: Serogroup C: Day 30 (n=49,47)	9304 (5532 to 15649)	3283 (1680 to 6415)		
rSBA: Serogroup Y: Day 0 (n=45,46)	6.86 (3.33 to 14.1)	8.24 (3.94 to 17.3)		

rSBA: Serogroup Y: Day 30 (n=49,47)	4274 (2640 to 6917)	1119 (529 to 2366)		
rSBA: Serogroup W: Day 0 (n=48,46)	11.6 (5.55 to 24.4)	12.4 (5.04 to 30.4)		
rSBA: Serogroup W: Day 30 (n=49,47)	6626 (3243 to 13539)	2304 (925 to 5739)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 3 and Group 4: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 3 and Group 4: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W[4]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Percentages are rounded off to the tenth decimal place. Percentage of participants who achieved antibody titers ≥1:4 and ≥1:8 by hSBA and ≥1:8 and ≥1:128 by rSBA are reported. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[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: Only participants in Group 3 and Group 4 of the study were analyzed in this endpoint.

End point values	Group 3: MenACYW Conjugate Vaccine	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	96		
Units: percentage of participants				
number (confidence interval 95%)				
hSBA: Serogroup A: Day 0: ≥1:4 (n=97,96)	94.8 (88.4 to 98.3)	93.8 (86.9 to 97.7)		
hSBA: Serogroup A: Day 0: ≥1:8 (n=97,96)	82.5 (73.4 to 89.4)	77.1 (67.4 to 85.0)		
hSBA: Serogroup A: Day 30: ≥1:4 (n=96,96)	89.6 (81.7 to 94.9)	96.9 (91.1 to 99.4)		
hSBA: Serogroup A: Day 30: ≥1:8 (n=96,96)	82.3 (73.2 to 89.3)	86.5 (78.0 to 92.6)		
hSBA: Serogroup C: Day 0: ≥1:4 (n=97,96)	71.1 (61.0 to 79.9)	75.0 (65.1 to 83.3)		
hSBA: Serogroup C: Day 0: ≥1:8 (n=97,96)	53.6 (43.2 to 63.8)	50.0 (39.6 to 60.4)		
hSBA: Serogroup C: Day 30: ≥1:4 (n=97,96)	97.9 (92.7 to 99.7)	92.7 (85.6 to 97.0)		

hSBA: Serogroup C: Day 30: ≥1:8 (n=97,96)	95.9 (89.8 to 98.9)	89.6 (81.7 to 94.9)		
hSBA: Serogroup Y: Day 0: ≥1:4 (n=97,96)	45.4 (35.2 to 55.8)	51.0 (40.6 to 61.4)		
hSBA: Serogroup Y: Day 0: ≥1:8 (n=97,96)	36.1 (26.6 to 46.5)	40.6 (30.7 to 51.1)		
hSBA: Serogroup Y: Day 30: ≥1:4 (n=97,96)	93.8 (87.0 to 97.7)	83.3 (74.4 to 90.2)		
hSBA: Serogroup Y: Day 30: ≥1:8 (n=97,96)	93.8 (87.0 to 97.7)	79.2 (69.7 to 86.8)		
hSBA: Serogroup W: Day 0: ≥1:4 (n=97,96)	45.4 (35.2 to 55.8)	54.2 (43.7 to 64.4)		
hSBA: Serogroup W: Day 0: ≥1:8 (n=97,96)	30.9 (21.9 to 41.1)	38.5 (28.8 to 49.0)		
hSBA: Serogroup W: Day 30: ≥1:4 (n=97,96)	91.8 (84.4 to 96.4)	90.6 (82.9 to 95.6)		
hSBA: Serogroup W: Day 30: ≥1:8 (n=97,96)	89.7 (81.9 to 94.9)	79.2 (69.7 to 86.8)		
rSBA: Serogroup A: Day 0: ≥1:8 (n=48,47)	68.8 (53.7 to 81.3)	55.3 (40.1 to 69.8)		
rSBA: Serogroup A: Day 0: ≥1:128 (n=48,47)	56.3 (41.2 to 70.5)	46.8 (32.1 to 61.9)		
rSBA: Serogroup A: Day 30: ≥1:8 (n=49,47)	98.0 (89.1 to 99.9)	100 (92.5 to 100)		
rSBA: Serogroup A: Day 30: ≥1:128 (n=49,47)	98.0 (89.1 to 99.9)	97.9 (88.7 to 99.9)		
rSBA: Serogroup C: Day 0: ≥1:8 (n=49,47)	30.6 (18.3 to 45.4)	21.3 (10.7 to 35.7)		
rSBA: Serogroup C: Day 0: ≥1:128 (n=49,47)	16.3 (7.3 to 29.7)	10.6 (3.5 to 23.1)		
rSBA: Serogroup C: Day 30: ≥1:8 (n=49,47)	98.0 (89.1 to 99.9)	93.6 (82.5 to 98.7)		
rSBA: Serogroup C: Day 30: ≥1:128 (n=49,47)	98.0 (89.1 to 99.9)	93.6 (82.5 to 98.7)		
rSBA: Serogroup Y: Day 0: ≥1:8 (n=45,46)	20.0 (9.6 to 34.6)	26.1 (14.3 to 41.1)		
rSBA: Serogroup Y: Day 0: ≥1:128 (n=45,46)	20.0 (9.6 to 34.6)	21.7 (10.9 to 36.4)		
rSBA: Serogroup Y: Day 30: ≥1:8 (n=49,47)	98.0 (89.1 to 99.9)	89.4 (76.9 to 96.5)		
rSBA: Serogroup Y: Day 30: ≥1:128 (n=49,47)	98.0 (89.1 to 99.9)	89.4 (76.9 to 96.5)		
rSBA: Serogroup W: Day 0: ≥1:8 (n=48,46)	33.3 (20.4 to 48.4)	30.4 (17.7 to 45.8)		
rSBA: Serogroup W: Day 0: ≥1:128 (n=48,46)	31.3 (18.7 to 46.3)	28.3 (16.0 to 43.5)		
rSBA: Serogroup W: Day 30: ≥1:8 (n=49,47)	95.9 (86.0 to 99.5)	89.4 (76.9 to 96.5)		
rSBA: Serogroup W: Day 30: ≥1:128 (n=49,47)	93.9 (83.1 to 98.7)	87.2 (74.3 to 95.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 5 + 7 and Group 6 + 8: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 5 + 7 and Group 6 + 8: Geometric Mean Titers of

	Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. As pre-specified in protocol, the endpoint was assessed in children and adolescents aged 2 to 17 years in India and RSA as combined groups: Group 5 + Group 7 and Group 6 + Group 8 as they received the same dose of MenACYW conjugate vaccine and Menactra® respectively. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

End point values	Group 5 + Group 7: MenACYW Conjugate Vaccine	Group 6 + Group 8: Menactra®		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	445	445		
Units: titer				
geometric mean (confidence interval 95%)				
hSBA: Serogroup A: Day 0 (n=445,445)	7.40 (6.79 to 8.07)	7.21 (6.66 to 7.80)		
hSBA: Serogroup A: Day 30 (n=443,443)	56.1 (48.5 to 65.0)	36.3 (31.0 to 42.5)		
hSBA: Serogroup C: Day 0 (n=445,445)	3.97 (3.63 to 4.34)	3.78 (3.46 to 4.13)		
hSBA: Serogroup C: Day 30 (n=445,443)	600 (521 to 692)	47.3 (38.3 to 58.4)		
hSBA: Serogroup Y: Day 0 (n=443,445)	3.50 (3.13 to 3.91)	3.50 (3.14 to 3.91)		
hSBA: Serogroup Y: Day 30 (n=445,443)	167 (145 to 191)	46.2 (39.3 to 54.3)		
hSBA: Serogroup W: Day 0 (n=445,445)	4.31 (3.88 to 4.78)	4.04 (3.65 to 4.48)		
hSBA: Serogroup W: Day 30 (n=445,445)	121 (106 to 137)	35.4 (30.4 to 41.1)		
rSBA: Serogroup A: Day 0 (n=186,189)	308 (199 to 478)	387 (260 to 577)		
rSBA: Serogroup A: Day 30 (n=191,189)	10561 (9223 to 12094)	8313 (7275 to 9499)		
rSBA: Serogroup C: Day 0 (n=191,190)	3.56 (2.91 to 4.36)	3.73 (3.02 to 4.62)		
rSBA: Serogroup C: Day 30 (n=191,189)	14430 (11923 to 17463)	1199 (869 to 1655)		
rSBA: Serogroup Y: Day 0 (n=181,182)	17.3 (11.5 to 26.2)	21.9 (14.4 to 33.4)		
rSBA: Serogroup Y: Day 30 (n=191,188)	15404 (13409 to 17696)	5966 (4850 to 7339)		
rSBA: Serogroup W: Day 0 (n=189,189)	7.01 (5.00 to 9.83)	7.46 (5.36 to 10.4)		
rSBA: Serogroup W: Day 30 (n=191,189)	19644 (16338 to 23618)	6598 (5160 to 8437)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 5 and Group 6: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 5 and Group 6: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W[5]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only participants in Group 5 and Group 6 of the study were analyzed in this endpoint.

End point values	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	228		
Units: titer				
geometric mean (confidence interval 95%)				
hSBA: Serogroup A: Day 0 (n=222,228)	7.33 (6.50 to 8.26)	7.71 (6.94 to 8.58)		
hSBA: Serogroup A: Day 30 (n=220,228)	70.3 (56.5 to 87.6)	40.9 (32.8 to 51.1)		
hSBA: Serogroup C: Day 0 (n=222,228)	3.36 (3.00 to 3.76)	3.17 (2.84 to 3.55)		
hSBA: Serogroup C: Day 30 (n=222,228)	595 (494 to 716)	38.3 (28.4 to 51.6)		
hSBA: Serogroup Y: Day 0 (n=222,228)	3.32 (2.84 to 3.88)	3.12 (2.70 to 3.60)		
hSBA: Serogroup Y: Day 30 (n=222,228)	119 (97.4 to 145)	27.1 (21.7 to 33.8)		
hSBA: Serogroup W: Day 0 (n=222,228)	3.23 (2.86 to 3.65)	2.85 (2.56 to 3.17)		
hSBA: Serogroup W: Day 30 (n=222,228)	92.8 (78.7 to 109)	24.3 (19.8 to 29.7)		
rSBA: Serogroup A: Day 0 (n=92,98)	159 (81.9 to 310)	337 (188 to 605)		
rSBA: Serogroup A: Day 30 (n=97,99)	11462 (9425 to 13938)	6877 (5755 to 8217)		

rSBA: Serogroup C: Day 0 (n=97,99)	3.09 (2.39 to 4.01)	2.98 (2.40 to 3.70)		
rSBA: Serogroup C: Day 30 (n=97,99)	11139 (8843 to 14030)	659 (413 to 1052)		
rSBA: Serogroup Y: Day 0 (n=87,91)	11.4 (6.25 to 20.6)	18.8 (10.4 to 33.7)		
rSBA: Serogroup Y: Day 30 (n=97,98)	15696 (12565 to 19609)	4522 (3316 to 6168)		
rSBA: Serogroup W: Day 0 (n=95,98)	6.62 (4.10 to 10.7)	7.78 (4.78 to 12.7)		
rSBA: Serogroup W: Day 30 (n=97,99)	19037 (14748 to 24572)	4332 (2969 to 6320)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 5 and Group 6: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 5 and Group 6: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W[6]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Percentages are rounded off to the tenth decimal place. Percentage of participants who achieved antibody titers ≥1:4 and ≥1:8 by hSBA and ≥1:8 and ≥1:128 by rSBA are reported. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants in Group 5 and Group 6 of the study were analyzed in this endpoint.

End point values	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	228		
Units: percentage of participants				
number (confidence interval 95%)				
hSBA: Serogroup A: Day 0: ≥1:4 (n=222,228)	85.1 (79.8 to 89.5)	91.2 (86.8 to 94.6)		
hSBA: Serogroup A: Day 0: ≥1:8 (n=222,228)	60.8 (54.1 to 67.3)	63.6 (57.0 to 69.8)		
hSBA: Serogroup A: Day 30: ≥1:4 (n=220,228)	92.3 (87.9 to 95.4)	94.7 (91.0 to 97.3)		
hSBA: Serogroup A: Day 30: ≥1:8 (n=220,228)	89.5 (84.7 to 93.3)	83.8 (78.3 to 88.3)		
hSBA: Serogroup C: Day 0: ≥1:4 (n=222,228)	37.8 (31.4 to 44.6)	30.7 (24.8 to 37.1)		

hSBA: Serogroup C: Day 0: ≥1:8 (n=222,228)	19.8 (14.8 to 25.7)	18.4 (13.6 to 24.1)		
hSBA: Serogroup C: Day 30: ≥1:4 (n=222,228)	99.5 (97.5 to 100)	82.9 (77.4 to 87.5)		
hSBA: Serogroup C: Day 30: ≥1:8 (n=222,228)	99.5 (97.5 to 100)	72.8 (66.5 to 78.5)		
hSBA: Serogroup Y: Day 0: ≥1:4 (n=222,228)	21.2 (16.0 to 27.1)	18.9 (14.0 to 24.6)		
hSBA: Serogroup Y: Day 0: ≥1:8 (n=222,228)	16.2 (11.6 to 21.7)	13.6 (9.4 to 18.7)		
hSBA: Serogroup Y: Day 30: ≥1:4 (n=222,228)	94.1 (90.2 to 96.8)	83.8 (78.3 to 88.3)		
hSBA: Serogroup Y: Day 30: ≥1:8 (n=222,228)	93.7 (89.6 to 96.5)	76.8 (70.7 to 82.1)		
hSBA: Serogroup W: Day 0: ≥1:4 (n=222,228)	27.9 (22.1 to 34.3)	20.2 (15.2 to 26.0)		
hSBA: Serogroup W: Day 0: ≥1:8 (n=222,228)	18.9 (14.0 to 24.7)	13.6 (9.4 to 18.7)		
hSBA: Serogroup W: Day 30: ≥1:4 (n=222,228)	99.1 (96.8 to 99.9)	86.8 (81.8 to 90.9)		
hSBA: Serogroup W: Day 30: ≥1:8 (n=222,228)	98.2 (95.5 to 99.5)	82.0 (76.4 to 86.8)		
rSBA: Serogroup A: Day 0: ≥1:8 (n=92,98)	66.3 (55.7 to 75.8)	76.5 (66.9 to 84.5)		
rSBA: Serogroup A: Day 0: ≥1:128 (n=92,98)	62.0 (51.2 to 71.9)	73.5 (63.6 to 81.9)		
rSBA: Serogroup A: Day 30: ≥1:8 (n=97,99)	100 (96.3 to 100)	100 (96.3 to 100)		
rSBA: Serogroup A: Day 30: ≥1:128 (n=97,99)	100 (96.3 to 100)	100 (96.3 to 100)		
rSBA: Serogroup C: Day 0: ≥1:8 (n=97,99)	11.3 (5.8 to 19.4)	13.1 (7.2 to 21.4)		
rSBA: Serogroup C: Day 0: ≥1:128 (n=97,99)	5.2 (1.7 to 11.6)	4.0 (1.1 to 10.0)		
rSBA: Serogroup C: Day 30: ≥1:8 (n=97,99)	100 (96.3 to 100)	90.9 (83.4 to 95.8)		
rSBA: Serogroup C: Day 30: ≥1:128 (n=97,99)	100 (96.3 to 100)	85.9 (77.4 to 92.0)		
rSBA: Serogroup Y: Day 0: ≥1:8 (n=87,91)	28.7 (19.5 to 39.4)	40.7 (30.5 to 51.5)		
rSBA: Serogroup Y: Day 0: ≥1:128 (n=87,91)	28.7 (19.5 to 39.4)	38.5 (28.4 to 49.2)		
rSBA: Serogroup Y: Day 30: ≥1:8 (n=97,98)	100 (96.3 to 100)	98.0 (92.8 to 99.8)		
rSBA: Serogroup Y: Day 30: ≥1:128 (n=97,98)	100 (96.3 to 100)	98.0 (92.8 to 99.8)		
rSBA: Serogroup W: Day 0: ≥1:8 (n=95,98)	21.1 (13.4 to 30.6)	24.5 (16.4 to 34.2)		
rSBA: Serogroup W: Day 0: ≥1:128 (n=95,98)	21.1 (13.4 to 30.6)	24.5 (16.4 to 34.2)		
rSBA: Serogroup W: Day 30: ≥1:8 (n=97,99)	100 (96.3 to 100)	98.0 (92.9 to 99.8)		
rSBA: Serogroup W: Day 30: ≥1:128 (n=97,99)	100 (96.3 to 100)	97.0 (91.4 to 99.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 7 and Group 8: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 7 and Group 8: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, Y, and W[7]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

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: Only participants in Group 7 and Group 8 of the study were analyzed in this endpoint.

End point values	Group 7: MenACYW Conjugate Vaccine	Group 8: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	217		
Units: titer				
geometric mean (confidence interval 95%)				
hSBA: Serogroup A: Day 0 (n=223, 217)	7.47 (6.59 to 8.47)	6.71 (5.97 to 7.55)		
hSBA: Serogroup A: Day 30 (n=223, 215)	44.9 (37.1 to 54.4)	31.9 (25.5 to 40.0)		
hSBA: Serogroup C: Day 0 (n=223, 217)	4.69 (4.10 to 5.36)	4.55 (3.97 to 5.20)		
hSBA: Serogroup C: Day 30 (n=223, 215)	606 (488 to 751)	59.2 (44.0 to 79.7)		
hSBA: Serogroup Y: Day 0 (n=221, 217)	3.69 (3.13 to 4.34)	3.96 (3.35 to 4.69)		
hSBA: Serogroup Y: Day 30 (n=223, 215)	233 (195 to 279)	81.5 (66.0 to 101)		
hSBA: Serogroup W: Day 0 (n=223, 217)	5.74 (4.89 to 6.74)	5.85 (4.97 to 6.88)		
hSBA: Serogroup W: Day 30 (n=223, 217)	157 (129 to 191)	52.5 (42.3 to 65.2)		
rSBA: Serogroup A: Day 0 (n=94, 91)	589 (338 to 1026)	450 (260 to 778)		
rSBA: Serogroup A: Day 30 (n=94, 90)	9706 (8032 to 11729)	10242 (8432 to 12440)		
rSBA: Serogroup C: Day 0 (n=94, 91)	4.12 (3.00 to 5.66)	4.77 (3.28 to 6.93)		
rSBA: Serogroup C: Day 30 (n=94, 90)	18848 (13953 to 25460)	2317 (1544 to 3476)		
rSBA: Serogroup Y: Day 0 (n=94, 91)	25.6 (14.6 to 45.2)	25.7 (13.9 to 47.3)		
rSBA: Serogroup Y: Day 30 (n=94, 90)	15108 (12775 to 17865)	8067 (6207 to 10483)		
rSBA: Serogroup W: Day 0 (n=94, 91)	7.43 (4.57 to 12.1)	7.14 (4.55 to 11.2)		

rSBA: Serogroup W: Day 30 (n=94, 90)	20290 (15479 to 26598)	10481 (7890 to 13924)		

Statistical analyses

No statistical analyses for this end point

Secondary: Group 7 and Group 8: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W

End point title	Group 7 and Group 8: Percentage of Participants who Achieved Antibody Titers ≥Pre-defined Thresholds Against Meningococcal Serogroups A, C, Y, and W[8]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W were measured by hSBA and rSBA. Percentages are rounded off to the tenth decimal place. Percentage of participants who achieved antibody titers ≥1:4 and ≥1:8 by hSBA and ≥1:8 and ≥1:128 by rSBA are reported. Analysis was performed on the PPAS which was a subset of the FAS. The FAS was the subset of randomized participants who received at least 1 dose of the study vaccine and had a valid post-vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup at the specified timepoint.

End point type	Secondary

End point timeframe:

Day 0 (pre-vaccination) and Day 30 (30 days post-vaccination on Day 0)

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: Only participants in Group 7 and Group 8 of the study were analyzed in this endpoint.

End point values	Group 7: MenACYW Conjugate Vaccine	Group 8: Menactra®		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	217		
Units: percentage of participants				
number (confidence interval 95%)				
hSBA: Serogroup A: Day 0: ≥1:4 (n=223,217)	88.8 (83.9 to 92.6)	86.6 (81.4 to 90.9)		
hSBA: Serogroup A: Day 0: ≥1:8 (n=223,217)	61.0 (54.2 to 67.4)	57.6 (50.7 to 64.3)		
hSBA: Serogroup A: Day 30: ≥1:4 (n=223,215)	96.9 (93.6 to 98.7)	93.5 (89.3 to 96.4)		
hSBA: Serogroup A: Day 30: ≥1:8 (n=223,215)	89.7 (84.9 to 93.3)	82.3 (76.6 to 87.2)		
hSBA: Serogroup C: Day 0: ≥1:4 (n=223,217)	58.3 (51.5 to 64.8)	57.1 (50.3 to 63.8)		
hSBA: Serogroup C: Day 0: ≥1:8 (n=223,217)	32.3 (26.2 to 38.9)	30.4 (24.4 to 37.0)		
hSBA: Serogroup C: Day 30: ≥1:4 (n=223,215)	99.6 (97.5 to 100)	93.0 (88.8 to 96.0)		
hSBA: Serogroup C: Day 30: ≥1:8 (n=223,215)	99.1 (96.8 to 99.9)	82.8 (77.1 to 87.6)		
hSBA: Serogroup Y: Day 0: ≥1:4 (n=221,217)	28.1 (22.2 to 34.5)	32.3 (26.1 to 38.9)		

hSBA: Serogroup Y: Day 0: ≥1:8 (n=221,217)	21.3 (16.1 to 27.3)	25.3 (19.7 to 31.7)		
hSBA: Serogroup Y: Day 30: ≥1:4 (n=223,215)	99.6 (97.5 to 100)	95.8 (92.2 to 98.1)		
hSBA: Serogroup Y: Day 30: ≥1:8 (n=223,215)	99.6 (97.5 to 100)	94.9 (91.0 to 97.4)		
hSBA: Serogroup W: Day 0: ≥1:4 (n=223,217)	53.4 (46.6 to 60.1)	55.3 (48.4 to 62.0)		
hSBA: Serogroup W: Day 0: ≥1:8 (n=223,217)	42.2 (35.6 to 48.9)	41.0 (34.4 to 47.9)		
hSBA: Serogroup W: Day 30: ≥1:4 (n=223,217)	99.1 (96.8 to 99.9)	94.9 (91.1 to 97.4)		
hSBA: Serogroup W: Day 30: ≥1:8 (n=223,217)	99.1 (96.8 to 99.9)	93.5 (89.4 to 96.4)		
rSBA: Serogroup A: Day 0: ≥1:8 (n=94,91)	84.0 (75.0 to 90.8)	83.5 (74.3 to 90.5)		
rSBA: Serogroup A: Day 0: ≥1:128 (n=94,91)	81.9 (72.6 to 89.1)	80.2 (70.6 to 87.8)		
rSBA: Serogroup A: Day 30: ≥1:8 (n=94,90)	100 (96.2 to 100)	100 (96.0 to 100)		
rSBA: Serogroup A: Day 30: ≥1:128 (n=94,90)	100 (96.2 to 100)	100 (96.0 to 100)		
rSBA: Serogroup C: Day 0: ≥1:8 (n=94,91)	19.1 (11.8 to 28.6)	19.8 (12.2 to 29.4)		
rSBA: Serogroup C: Day 0: ≥1:128 (n=94,91)	6.4 (2.4 to 13.4)	9.9 (4.6 to 17.9)		
rSBA: Serogroup C: Day 30: ≥1:8 (n=94,90)	100 (96.2 to 100)	98.9 (94.0 to 100)		
rSBA: Serogroup C: Day 30: ≥1:128 (n=94,90)	100 (96.2 to 100)	96.7 (90.6 to 99.3)		
rSBA: Serogroup Y: Day 0: ≥1:8 (n=94,91)	47.9 (37.5 to 58.4)	46.2 (35.6 to 56.9)		
rSBA: Serogroup Y: Day 0: ≥1:128 (n=94,91)	46.8 (36.4 to 57.4)	40.7 (30.5 to 51.5)		
rSBA: Serogroup Y: Day 30: ≥1:8 (n=94,90)	100 (96.2 to 100)	98.9 (94.0 to 100)		
rSBA: Serogroup Y: Day 30: ≥1:128 (n=94,90)	100 (96.2 to 100)	98.9 (94.0 to 100)		
rSBA: Serogroup W: Day 0: ≥1:8 (n=94,91)	24.5 (16.2 to 34.4)	26.4 (17.7 to 36.7)		
rSBA: Serogroup W: Day 0: ≥1:128 (n=94,91)	22.3 (14.4 to 32.1)	23.1 (14.9 to 33.1)		
rSBA: Serogroup W: Day 30: ≥1:8 (n=94,90)	100 (96.2 to 100)	100 (96.0 to 100)		
rSBA: Serogroup W: Day 30: ≥1:128 (n=94,90)	100 (96.2 to 100)	100 (96.0 to 100)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From the first study vaccine administration (Day 0) up to 30 days post-vaccination on Day 0, mean study subject duration was 33 days for Groups 1 to 4, 34 days for Groups 5 and 6, and 35 days for Groups 7 and 8.

Adverse event reporting additional description:

Analysis was performed on safety analysis set which was defined as those participants who received at least 1 dose of the study vaccine and had any safety data available. All participants had their safety analyzed according to the vaccine they actually received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine

Reporting group description:

Adult participants aged 18 to 55 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

Reporting group title	Group 3: MenACYW Conjugate Vaccine

Reporting group description:

Adult participants aged ≥56 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

Reporting group title	Group 8: Menactra®

Reporting group description:

Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Reporting group title	Group 5: MenACYW Conjugate Vaccine

Reporting group description:

Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

Reporting group title	Group 6: Menactra®

Reporting group description:

Children and adolescent participants aged 2 to 17 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Reporting group title	Group 7: MenACYW Conjugate Vaccine

Reporting group description:

Children and adolescent participants aged 2 to 17 years in RSA received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 0.

Reporting group title	Group 2: Menactra®

Reporting group description:

Adult participants aged 18 to 55 years in India received a single dose of 0.5 mL Menactra® as an IM injection on Day 0.

Reporting group title	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine

Reporting group description:

Adult participants aged ≥56 years in India received a single dose of 0.5 mL Quadri Meningo™ or any locally available licensed meningococcal vaccine as an IM injection on Day 0.

Serious adverse events	Group 1: MenACYW Conjugate Vaccine	Group 3: MenACYW Conjugate Vaccine	Group 8: Menactra®
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 98 (1.02%)	0 / 100 (0.00%)	0 / 227 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Dengue Fever			
subjects affected / exposed	0 / 98 (0.00%)	0 / 100 (0.00%)	0 / 227 (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
Covid-19			
subjects affected / exposed	1 / 98 (1.02%)	0 / 100 (0.00%)	0 / 227 (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	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®	Group 7: MenACYW Conjugate Vaccine
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 232 (0.43%)	0 / 232 (0.00%)	0 / 229 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Dengue Fever			
subjects affected / exposed	1 / 232 (0.43%)	0 / 232 (0.00%)	0 / 229 (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
Covid-19			
subjects affected / exposed	0 / 232 (0.00%)	0 / 232 (0.00%)	0 / 229 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 2: Menactra®	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Infections and infestations			
Dengue Fever			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Covid-19			
subjects affected / exposed	0 / 100 (0.00%)	0 / 100 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 1: MenACYW Conjugate Vaccine	Group 3: MenACYW Conjugate Vaccine	Group 8: Menactra®
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 98 (32.65%)	18 / 100 (18.00%)	128 / 227 (56.39%)
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 98 (6.12%)	3 / 100 (3.00%)	57 / 227 (25.11%)
occurrences (all)	6	3	61
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	1 / 98 (1.02%)	0 / 100 (0.00%)	27 / 227 (11.89%)
occurrences (all)	1	0	27
Malaise			
subjects affected / exposed	6 / 98 (6.12%)	1 / 100 (1.00%)	44 / 227 (19.38%)
occurrences (all)	6	1	44
Injection Site Swelling			
subjects affected / exposed	1 / 98 (1.02%)	0 / 100 (0.00%)	37 / 227 (16.30%)
occurrences (all)	1	0	37
Pyrexia			
subjects affected / exposed	5 / 98 (5.10%)	4 / 100 (4.00%)	8 / 227 (3.52%)
occurrences (all)	5	4	8
Injection Site Pain			
subjects affected / exposed	27 / 98 (27.55%)	9 / 100 (9.00%)	82 / 227 (36.12%)
occurrences (all)	27	9	82
Musculoskeletal and connective tissue			

disorders			
Myalgia			
subjects affected / exposed	5 / 98 (5.10%)	2 / 100 (2.00%)	49 / 227 (21.59%)
occurrences (all)	5	2	49

Non-serious adverse events	Group 5: MenACYW Conjugate Vaccine	Group 6: Menactra®	Group 7: MenACYW Conjugate Vaccine
Total subjects affected by non-serious adverse events			
subjects affected / exposed	81 / 232 (34.91%)	43 / 232 (18.53%)	115 / 229 (50.22%)
Nervous system disorders			
Headache			
subjects affected / exposed	13 / 232 (5.60%)	3 / 232 (1.29%)	56 / 229 (24.45%)
occurrences (all)	13	3	57
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	1 / 232 (0.43%)	0 / 232 (0.00%)	28 / 229 (12.23%)
occurrences (all)	1	0	28
Malaise			
subjects affected / exposed	11 / 232 (4.74%)	4 / 232 (1.72%)	45 / 229 (19.65%)
occurrences (all)	11	4	45
Injection Site Swelling			
subjects affected / exposed	1 / 232 (0.43%)	1 / 232 (0.43%)	25 / 229 (10.92%)
occurrences (all)	1	1	25
Pyrexia			
subjects affected / exposed	37 / 232 (15.95%)	16 / 232 (6.90%)	8 / 229 (3.49%)
occurrences (all)	37	16	8
Injection Site Pain			
subjects affected / exposed	52 / 232 (22.41%)	29 / 232 (12.50%)	85 / 229 (37.12%)
occurrences (all)	52	29	85
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	7 / 232 (3.02%)	3 / 232 (1.29%)	46 / 229 (20.09%)
occurrences (all)	7	3	46

Non-serious adverse events	Group 2: Menactra®	Group 4: Quadri Meningo™/Local Licensed Meningococcal Vaccine	
Total subjects affected by non-serious adverse events			

subjects affected / exposed	26 / 100 (26.00%)	21 / 100 (21.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	6 / 100 (6.00%)	3 / 100 (3.00%)	
occurrences (all)	6	3	
General disorders and administration site conditions			
Injection Site Erythema			
subjects affected / exposed	0 / 100 (0.00%)	1 / 100 (1.00%)	
occurrences (all)	0	1	
Malaise			
subjects affected / exposed	5 / 100 (5.00%)	1 / 100 (1.00%)	
occurrences (all)	5	1	
Injection Site Swelling			
subjects affected / exposed	0 / 100 (0.00%)	2 / 100 (2.00%)	
occurrences (all)	0	2	
Pyrexia			
subjects affected / exposed	2 / 100 (2.00%)	4 / 100 (4.00%)	
occurrences (all)	2	4	
Injection Site Pain			
subjects affected / exposed	24 / 100 (24.00%)	14 / 100 (14.00%)	
occurrences (all)	24	14	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	6 / 100 (6.00%)	0 / 100 (0.00%)	
occurrences (all)	6	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

None reported