Clinical trial results:
A Phase III, open-label, single-center study to describe the immunogenicity and safety of a single dose of MenACYW Conjugate Vaccine in participants aged 12 months and older in Vietnam

Summary

EudraCT number	2021-001699-41
Trial protocol	Outside EU/EEA
Global end of trial date	31 March 2024

Results information

Result version number	v1 (current)
This version publication date	14 September 2025
First version publication date	14 September 2025

Trial information

Trial identification

Sponsor protocol code	MEQ00074

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06228586
WHO universal trial number (UTN)	U1111-1256-9172

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 April 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 March 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the antibody responses to meningococcal serogroups A, C, W, and Y before and 30 days after the administration of a single dose of meningococcal polysaccharide (serogroups A, C, W, and Y) tetanus toxoid conjugate vaccine (MenACYW conjugate vaccine).

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	18 January 2024
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	Viet Nam: 447
Worldwide total number of subjects	447
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)	223
Children (2-11 years)	74
Adolescents (12-17 years)	47
Adults (18-64 years)	88
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 4 investigational sites (1 main site and 3 satellite sites) in Vietnam.

Pre-assignment

Screening details:

A total of 447 participants (223 participants aged 12-23 months and 224 participants aged >=24 months) 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

Are arms mutually exclusive?	Yes
Arm title	MenACYW Conjugate Vaccine: 12-23 Months of Age

Arm description:

Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	MenACYW Conjugate Vaccine
Investigational medicinal product code	
Other name	MenQuadfi
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACYW conjugate vaccine 0.5 mL IM injection was administered as a single dose in the anterolateral area of the thigh or deltoid muscle on Day 1.

Arm title	MenACYW Conjugate Vaccine: 24 Months of Age and Above

Arm description:

Participants aged >=24 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	MenACYW Conjugate Vaccine
Investigational medicinal product code	
Other name	MenQuadfi
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACYW conjugate vaccine 0.5 mL IM injection was administered as a single dose in the anterolateral area of the thigh or deltoid muscle on Day 1.

Number of subjects in period 1	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above
Started	223	224
Vaccinated	223	223
Completed	220	223
Not completed	3	1
Withdrawal by Participant or Parent/Guardian	3	1

Baseline characteristics

Reporting groups	
Reporting group title	MenACYW Conjugate Vaccine: 12-23 Months of Age
Reporting group description:	
Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1.	
Reporting group title	MenACYW Conjugate Vaccine: 24 Months of Age and Above
Reporting group description:	
Participants aged >=24 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.	

Reporting group values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above	Total
Number of subjects	223	224	447
Age Categorical Units: participants			
<=18 years	223	121	344
Between 18 and 65 years	0	88	88
>=65 years	0	15	15
Sex: Female, Male Units: participants			
Female	118	130	248
Male	105	94	199
Race and Ethnicity Not Collected Units: Subjects			
Not collected	223	224	447

End points

End points reporting groups

Reporting group title	MenACYW Conjugate Vaccine: 12-23 Months of Age
Reporting group description:	
Participants aged 12-23 months received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine as an intramuscular (IM) injection on Day 1.	
Reporting group title	MenACYW Conjugate Vaccine: 24 Months of Age and Above
Reporting group description:	
Participants aged >=24 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.	

Primary: Geometric Mean Titers (GMTs) of Antibodies Against Meningococcal Serogroups A, C, Y, and W

End point title	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 was measured in a serum bactericidal assay utilizing the human complement (hSBA). Analysis was performed on the per-protocol analysis set (PPAS) which 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.	
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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	221		
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1	4.44 (4.00 to 4.92)	7.58 (6.76 to 8.51)		
Serogroup A: Day 31	39.0 (32.9 to 46.2)	43.2 (34.6 to 54.1)		
Serogroup C: Day 1	2.61 (2.34 to 2.91)	5.65 (4.82 to 6.62)		
Serogroup C: Day 31	1226 (1076 to 1398)	895 (781 to 1026)		
Serogroup Y: Day 1	2.86 (2.55 to 3.20)	4.08 (3.47 to 4.78)		
Serogroup Y: Day 31	132 (112 to 156)	288 (244 to 340)		
Serogroup W: Day 1	2.26 (2.09 to 2.44)	4.33 (3.81 to 4.92)		
Serogroup W: Day 31	99.4 (85.6 to 115)	166 (139 to 198)		

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants With Serum Bactericidal Assay Using Human Complement Titers >=4-Fold Rise From Pre-Vaccination to Post-Vaccination[2]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post vaccination serology result.

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	221		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A	81.5 (75.4 to 86.6)	66.5 (59.9 to 72.7)		
Serogroup C	99.5 (97.2 to 100)	97.7 (94.8 to 99.3)		
Serogroup Y	96.5 (92.9 to 98.6)	95.5 (91.8 to 97.8)		
Serogroup W	94.5 (90.4 to 97.2)	95.5 (91.8 to 97.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Titers >=1:4 and >=1:8

End point title	Percentage of Participants With Serum Bactericidal Assay Using

	Human Complement Titers >=1:4 and >=1:8[3]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result.

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	221		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1: >=1:4	79.5 (73.2 to 84.9)	94.1 (90.2 to 96.8)		
Serogroup A: Day 1: >=1:8	25.0 (19.2 to 31.6)	59.7 (52.9 to 66.3)		
Serogroup A: Day 31: >=1:4	97.5 (94.3 to 99.2)	89.1 (84.3 to 92.9)		
Serogroup A: Day 31: >=1:8	93.5 (89.1 to 96.5)	84.6 (79.2 to 89.1)		
Serogroup C: Day 1: >=1:4	16.5 (11.6 to 22.4)	64.3 (57.6 to 70.6)		
Serogroup C: Day 1: >=1:8	8.5 (5.0 to 13.3)	38.5 (32.0 to 45.2)		
Serogroup C: Day 31: >=1:4	100 (98.2 to 100)	100 (98.3 to 100)		
Serogroup C: Day 31: >=1:8	100 (98.2 to 100)	100 (98.3 to 100)		
Serogroup Y: Day 1: >=1:4	21.0 (15.6 to 27.3)	35.3 (29.0 to 42.0)		
Serogroup Y: Day 1: >=1:8	15.5 (10.8 to 21.3)	26.2 (20.6 to 32.6)		
Serogroup Y: Day 31: >=1:4	99.5 (97.2 to 100)	99.1 (96.8 to 99.9)		
Serogroup Y: Day 31: >=1:8	98.5 (95.7 to 99.7)	99.1 (96.8 to 99.9)		
Serogroup W: Day 1: >=1:4	7.0 (3.9 to 11.5)	51.6 (44.8 to 58.3)		
Serogroup W: Day 1: >=1:8	4.0 (1.7 to 7.7)	32.1 (26.0 to 38.7)		
Serogroup W: Day 31: >=1:4	99.5 (97.2 to 100)	100 (98.3 to 100)		
Serogroup W: Day 31: >=1:8	98.5 (95.7 to 99.7)	100 (98.3 to 100)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Vaccine Seroresponse for Serogroups A, C, Y, and W

End point title	Percentage of Participants With Serum Bactericidal Assay Using Human Complement Vaccine Seroresponse for Serogroups A, C, Y, and W[4]

End point description:

Functional meningococcal antibody activity against serogroups A, C, Y, and W was measured by hSBA. hSBA vaccine seroresponse was defined as follows: for a participant with a pre-vaccination titer <1:8, the post-vaccination titer must be >=1:16, and for a participant with a pre-vaccination titer >=1:8, the post-vaccination titer must be at least 4-fold greater than the pre-vaccination titer. Percentages are rounded off to the tenth decimal place. Analysis was performed on the PPAS which was a subset of the FAS. The FAS included participants who received the study vaccine and had a valid post-vaccination serology result.

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	200	221		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A	81.5 (75.4 to 86.6)	66.5 (59.9 to 72.7)		
Serogroup C	99.5 (97.2 to 100)	97.7 (94.8 to 99.3)		
Serogroup Y	96.5 (92.9 to 98.6)	95.5 (91.8 to 97.8)		
Serogroup W	94.5 (90.4 to 97.2)	95.5 (91.8 to 97.8)		

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)[5]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. 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. Immediate events were recorded

to capture medically relevant unsolicited systemic AEs (including those related to the study vaccine administered) which occurred within the first 30 minutes after vaccination. The safety analysis set (SafAS) included participants who received the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

Up to 30 minutes 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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	223		
Units: participants	0	1		

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[6]

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 considered to be related to the study vaccine administered and were commonly inflammatory reactions. Systemic ARs were all ARs that were not injection site reactions and included systemic manifestations such as headache, fever, as well as localized or topical manifestations. The SafAS included participants who received the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

From the study vaccine administration (Day 1) up to 7 days post-vaccination, up to Day 8

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	223		
Units: participants				
Solicited injection site reactions	29	29		
Solicited systemic reactions	34	24		

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)[7]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. 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 other medically important event. An AESI (serious or non-serious) was one of scientific and medical concern specific to the Sponsor's study vaccine or program, for which ongoing monitoring and rapid communication by the investigator to the Sponsor was appropriate. The SafAS included participants who received the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

From the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	223		
Units: participants				
SAEs	3	2		
AESIs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Non-Serious Adverse Events

End point title	Number of Participants With Unsolicited Non-Serious Adverse Events[8]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. 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 onset window post-vaccination. The SafAS included participants who received the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

From the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

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, statistical analysis is not presented.

End point values	MenACYW Conjugate Vaccine: 12-23 Months of Age	MenACYW Conjugate Vaccine: 24 Months of Age and Above		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	223		
Units: participants	48	11		

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 the study vaccine administration (Day 1) up to 30 days post-vaccination (Day 31)

Adverse event reporting additional description:

Analysis was performed on the SafAS.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	28.0

Reporting groups

Reporting group title	MenACYW Conjugate Vaccine: 24 Months of Age and Above

Reporting group description:

Participants aged >=24 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

Reporting group title	MenACYW Conjugate Vaccine: 12-23 Months of Age

Reporting group description:

Participants aged 12-23 months received a single dose of 0.5 mL MenACYW conjugate vaccine as an IM injection on Day 1.

Serious adverse events	MenACYW Conjugate Vaccine: 24 Months of Age and Above	MenACYW Conjugate Vaccine: 12-23 Months of Age	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 223 (0.90%)	3 / 223 (1.35%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Rib Fracture			
subjects affected / exposed	1 / 223 (0.45%)	0 / 223 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 223 (0.00%)	1 / 223 (0.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			

subjects affected / exposed	0 / 223 (0.00%)	3 / 223 (1.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 223 (0.45%)	0 / 223 (0.00%)	
occurrences causally related to treatment / all	0 / 1	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	MenACYW Conjugate Vaccine: 24 Months of Age and Above	MenACYW Conjugate Vaccine: 12-23 Months of Age	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 223 (17.49%)	59 / 223 (26.46%)	
General disorders and administration site conditions			
Injection Site Pain			
subjects affected / exposed	23 / 223 (10.31%)	26 / 223 (11.66%)	
occurrences (all)	23	26	
Injection Site Erythema			
subjects affected / exposed	11 / 223 (4.93%)	13 / 223 (5.83%)	
occurrences (all)	11	13	
Crying			
subjects affected / exposed	0 / 223 (0.00%)	13 / 223 (5.83%)	
occurrences (all)	0	13	
Malaise			
subjects affected / exposed	13 / 223 (5.83%)	0 / 223 (0.00%)	
occurrences (all)	13	0	
Pyrexia			
subjects affected / exposed	7 / 223 (3.14%)	16 / 223 (7.17%)	
occurrences (all)	8	16	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	15 / 223 (6.73%)	0 / 223 (0.00%)	
occurrences (all)	15	0	
Infections and infestations			

Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	2 / 223 (0.90%) 2	22 / 223 (9.87%) 22	
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	0 / 223 (0.00%) 0	17 / 223 (7.62%) 17	

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