Clinical trial results:
Phase I Open-Label, Age De-escalation Safety and Immunogenicity Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine in Healthy Adolescents, Children, Toddlers, and Infants in China

Summary

EudraCT number	2025-000103-23
Trial protocol	Outside EU/EEA
Global end of trial date	22 October 2024

Results information

Result version number	v1 (current)
This version publication date	02 May 2025
First version publication date	02 May 2025

Trial information

Trial identification

Sponsor protocol code	MEQ00075

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1256-9026

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc.
Sponsor organisation address	Discovery Drive, Swiftwater, Pennsylvania, 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	27 March 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of meningococcal polysaccharide (serogroups A, C, Y, and W) tetanus toxoid (MenACYW) conjugate vaccine and the safety profiles of the control vaccines (locally-licensed MenAC conjugate vaccines: Royal or Green Bamboo)

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	12 August 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	China: 300
Worldwide total number of subjects	300
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)	180
Children (2-11 years)	100
Adolescents (12-17 years)	20
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted in China.

Pre-assignment

Screening details:

A total of 300 participants were randomly assigned to 1 of 10 study groups in 1:1 ratio in 5 Cohorts.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenACYW Conjugate Vaccine (7-17 Years)

Arm description:

Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

Arm title	Group 2: Green Bamboo’s MenAC Conjugate Vaccine (7-17 Years)

Arm description:

Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection on Day 1.

Arm type	Active comparator
Investigational medicinal product name	Green Bamboo’s MenAC Conjugate Vaccine
Investigational medicinal product code	
Other name	Mening A Con
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Green Bamboo’s MenAC conjugate vaccine 0.5 mL IM injection was administered as a single dose in the form of suspension on Day 1.

Arm title	Group 3: MenACYW Conjugate Vaccine (2-6 Years)

Arm description:

Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

Arm title	Group 4: Royal’s MenAC Conjugate Vaccine (2-6 Years)

Arm description:

Participants aged 2 to 6 years received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1.

Arm type	Active comparator
Investigational medicinal product name	Royal’s MenAC Conjugate Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Royal’s MenAC conjugate vaccine 0.5 mL IM injection was administered as a single dose in the form of lyophilized powder on Day 1.

Arm title	Group 5: MenACYW Conjugate Vaccine (12-23 Months)

Arm description:

Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine 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 form of liquid solution on Day 1.

Arm title	Group 6: Royal’s MenAC Conjugate Vaccine (12-23 Months)

Arm description:

Participants aged 12 to 23 months received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal’s MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product’s approved vaccination schedule. This second dose of Royal’s vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.

Arm type	Active comparator
Investigational medicinal product name	Royal’s MenAC Conjugate Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Royal’s MenAC conjugate vaccine 0.5 mL IM injection was administered as 2 doses in the form of lyophilized powder on Days 1 and 31.

Arm title	Group 7: MenACYW Conjugate Vaccine (6-11 Months)

Arm description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.

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 2 doses in the form of liquid solution on Days 1 and 31.

Arm title	Group 8: Royal’s MenAC Conjugate Vaccine (6-11 Months)

Arm description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal’s MenAC conjugate vaccine IM injection each on Days 1 and 31.

Arm type	Active comparator
Investigational medicinal product name	Royal’s MenAC Conjugate Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Royal’s MenAC conjugate vaccine 0.5 mL IM injection was administered as 2 doses in the form of lyophilized powder on Days 1 and 31.

Arm title	Group 9: MenACYW Conjugate Vaccine (3-5 Months)

Arm description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.

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 3 doses in the form of liquid solution on Days 1, 31 and 61.

Arm title	Group 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months)

Arm description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.

Arm type	Active comparator
Investigational medicinal product name	Green Bamboo’s MenAC Conjugate Vaccine
Investigational medicinal product code	
Other name	Mening A Con
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Green Bamboo’s MenAC conjugate vaccine 0.5 mL IM injection was administered as 3 doses in the form of suspension on Days 1, 31 and 61.

Number of subjects in period 1	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Started	30	30	30
Completed	30	30	30
Not completed	0	0	0
Randomized but did not receive vaccination	-	-	-

Number of subjects in period 1	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)
Started	30	30	30
Completed	30	30	30
Not completed	0	0	0
Randomized but did not receive vaccination	-	-	-

Number of subjects in period 1	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)	Group 9: MenACYW Conjugate Vaccine (3-5 Months)
Started	30	30	30
Completed	30	28	30
Not completed	0	2	0
Randomized but did not receive vaccination	-	2	-

Number of subjects in period 1	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months)
Started	30
Completed	30
Not completed	0
Randomized but did not receive vaccination	-

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenACYW Conjugate Vaccine (7-17 Years)
Reporting group description:	
Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine intramuscular (IM) injection on Day 1.	
Reporting group title	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)
Reporting group description:	
Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Reporting group description:	
Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Reporting group description:	
Participants aged 2 to 6 years received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 5: MenACYW Conjugate Vaccine (12-23 Months)
Reporting group description:	
Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)
Reporting group description:	
Participants aged 12 to 23 months received a single dose of 0.5 mL Royal's MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal's MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product's approved vaccination schedule. This second dose of Royal's vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.	
Reporting group title	Group 7: MenACYW Conjugate Vaccine (6-11 Months)
Reporting group description:	
Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.	
Reporting group title	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Reporting group description:	
Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal's MenAC conjugate vaccine IM injection each on Days 1 and 31.	
Reporting group title	Group 9: MenACYW Conjugate Vaccine (3-5 Months)
Reporting group description:	
Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.	
Reporting group title	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months)
Reporting group description:	
Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.	

Reporting group values	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Number of subjects	30	30	30

Age Categorical Units: Participants			

Age Continuous Units: months			
arithmetic mean	124.8	136.8	61.2
standard deviation	± 1.7	± 2.4	± 1.2
Gender Categorical Units: Participants			
Female	22	17	13
Male	8	13	17

Reporting group values	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)
Number of subjects	30	30	30
Age Categorical Units: Participants			

Age Continuous Units: months			
arithmetic mean	61.2	20.7	19.4
standard deviation	± 1.1	± 2.3	± 2.9
Gender Categorical Units: Participants			
Female	16	14	14
Male	14	16	16

Reporting group values	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)	Group 9: MenACYW Conjugate Vaccine (3-5 Months)
Number of subjects	30	30	30
Age Categorical Units: Participants			

Age Continuous Units: months			
arithmetic mean	7.0	6.9	4.0
standard deviation	± 1.4	± 1.3	± 0.8
Gender Categorical Units: Participants			
Female	14	13	17
Male	16	17	13

Reporting group values	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5 Months)	Total	
Number of subjects	30	300	
Age Categorical Units: Participants			

Age Continuous Units: months			
arithmetic mean	4.1		
standard deviation	± 0.8	-	
Gender Categorical Units: Participants			
Female	18	158	
Male	12	142	

End points

End points reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine (7-17 Years)
Reporting group description:	
Participants aged 7 to 17 years received a single dose of 0.5 milliliter (mL) MenACYW conjugate vaccine intramuscular (IM) injection on Day 1.	
Reporting group title	Group 2: Green Bamboo’s MenAC Conjugate Vaccine (7-17 Years)
Reporting group description:	
Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Reporting group description:	
Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 4: Royal’s MenAC Conjugate Vaccine (2-6 Years)
Reporting group description:	
Participants aged 2 to 6 years received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 5: MenACYW Conjugate Vaccine (12-23 Months)
Reporting group description:	
Participants aged 12 to 23 months received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.	
Reporting group title	Group 6: Royal’s MenAC Conjugate Vaccine (12-23 Months)
Reporting group description:	
Participants aged 12 to 23 months received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal’s MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product’s approved vaccination schedule. This second dose of Royal’s vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.	
Reporting group title	Group 7: MenACYW Conjugate Vaccine (6-11 Months)
Reporting group description:	
Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.	
Reporting group title	Group 8: Royal’s MenAC Conjugate Vaccine (6-11 Months)
Reporting group description:	
Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal’s MenAC conjugate vaccine IM injection each on Days 1 and 31.	
Reporting group title	Group 9: MenACYW Conjugate Vaccine (3-5 Months)
Reporting group description:	
Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.	
Reporting group title	Group 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months)
Reporting group description:	
Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.	

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

End point title	Number of Participants With Immediate Unsolicited Adverse Events (AEs)[1]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that was, pre-listed in the case report form (CRF) in terms of diagnosis and onset window post-vaccination. All participants were observed for 30 minutes after vaccination, and any unsolicited AEs occurred during that time were recorded as immediate unsolicited AEs. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

Up to 30 minutes after each and any study vaccination

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	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	30
Units: participants	0	0	0	0

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	28
Units: participants	0	0	0	0

End point values	Group 9: MenACYW Conjugate Vaccine (3-5 Months)	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: participants	0	2		

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[2]

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 and considered as related to the study intervention administered. An injection site reaction was an AR at and around the injection site and were commonly inflammatory reactions. Solicited systemic reactions were systemic AEs and those occurring during the specified collection period were always considered related to the intervention even if there was evidence of alternative etiology. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

Up to 7 days after each and any study vaccination

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	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	30
Units: participants				
Injection site reactions	7	9	9	5
Systemic reactions	3	2	5	2

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	28
Units: participants				
Injection site reactions	2	2	3	1
Systemic reactions	7	6	17	8

End point values	Group 9: MenACYW Conjugate Vaccine (3-5 Months)	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: participants				
Injection site reactions	1	3		
Systemic reactions	19	12		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs)

End point title	Number of Participants With Serious Adverse Events (SAEs)[3]

End point description:

An SAE was defined as 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. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

From date of first vaccination (Day 1) up to 6 months after the last study vaccination, approximately 180 days for Groups 1 to 6, 210 days for Groups 7, 8 and 240 days for Groups 9, 10

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	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	30
Units: participants	0	1	4	3

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	28
Units: participants	7	8	13	14

End point values	Group 9: MenACYW Conjugate	Group 10: Green Bamboo's		

	Vaccine (3-5 Months)	Conjugate Vaccine (3-5 Months)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: participants	15	14		

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[4]

End point description:

An AE was any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An unsolicited AE was an observed AE that did not fulfill the conditions of solicited reactions, that was, pre-listed in the CRF in terms of diagnosis and/or onset window post-vaccination. Analysis was performed on the safety analysis set which included participants who received at least 1 dose of the study vaccine and had any safety data available.

End point type	Primary

End point timeframe:

Up to 30 days after each and any study vaccination

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	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	30
Units: participants	6	7	11	10

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	30	30	28
Units: participants	15	15	26	23

End point values	Group 9: MenACYW	Group 10: Green Bamboo'		

	Conjugate Vaccine (3-5 Months)	s MenAC Conjugate Vaccine (3-5 Months)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	30	30		
Units: participants	28	25		

Statistical analyses

No statistical analyses for this end point

Secondary: All Groups: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Rabbit Complement (rSBA)

End point title	All Groups: Percentage of Participants With Vaccine Seroresponse by Serum Bactericidal Assay Using Rabbit Complement (rSBA)

End point description:

The rSBA vaccine seroresponse to meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and to serogroups A and C for comparators was defined as follows: 30 days post-vaccination rSBA titers >=1:8 for participants with pre-vaccination rSBA titers <1:8 OR at least 4-fold increase in rSBA titers from pre to 30 days post-vaccination for participants with pre vaccination rSBA titers >=1:8. Analysis was performed on the per-protocol analysis set which was the subset of full analysis set (FAS: participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result). Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

Day 1 (all Groups) and Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10

End point values	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	25	29
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	82.1 (63.1 to 93.9)	19.2 (6.6 to 39.4)	88.0 (68.8 to 97.5)	82.8 (64.2 to 94.2)
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	96.4 (81.7 to 99.9)	30.8 (14.3 to 51.8)	100 (86.3 to 100)	100 (88.1 to 100)
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	89.3 (71.8 to 97.7)	9999 (9999 to 9999)	92.0 (74.0 to 99.0)	9999 (9999 to 9999)
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	96.4 (81.7 to 99.9)	9999 (9999 to 9999)	96.0 (79.6 to 99.9)	9999 (9999 to 9999)

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	27	25	21
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	96.6 (82.2 to 99.9)	88.9 (70.8 to 97.6)	96.0 (79.6 to 99.9)	76.2 (52.8 to 91.8)
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	100 (88.1 to 100)	100 (87.2 to 100)	100 (86.3 to 100)	100 (83.9 to 100)
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	89.7 (72.6 to 97.8)	9999 (9999 to 9999)	88.0 (68.8 to 97.5)	9999 (9999 to 9999)
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	93.1 (77.2 to 99.2)	9999 (9999 to 9999)	96.0 (79.6 to 99.9)	9999 (9999 to 9999)

End point values	Group 9: MenACYW Conjugate Vaccine (3-5 Months)	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	94.7 (74.0 to 99.9)	11.1 (1.4 to 34.7)		
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	100 (82.4 to 100)	38.9 (17.3 to 64.3)		
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	100 (82.4 to 100)	9999 (9999 to 9999)		
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	100 (82.4 to 100)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: All Groups: Geometric Mean Titers Against Meningococcal Serogroups as Measured by rSBA

End point title	All Groups: Geometric Mean Titers Against Meningococcal Serogroups as Measured by rSBA

End point description:

Antibody titers against meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and serogroups A and C for comparators were measured by rSBA. Analysis was performed on the per-protocol analysis set which was the subset of FAS which included participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result. Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'.

End point type	Secondary

End point timeframe:

30 days after vaccination (Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10)

End point values	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	25	29
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	742 (517 to 1066)	60.7 (29.1 to 126)	572 (400 to 817)	349 (243 to 502)
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	565 (370 to 864)	3.89 (1.89 to 8.03)	695 (463 to 1042)	433 (325 to 577)
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	353 (205 to 609)	9999 (9999 to 9999)	294 (209 to 413)	9999 (9999 to 9999)
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	238 (163 to 346)	9999 (9999 to 9999)	118 (74.7 to 186)	9999 (9999 to 9999)

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	27	25	21
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	256 (160 to 409)	91.7 (42.0 to 200)	89.3 (47.8 to 167)	40.3 (13.0 to 125)
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	550 (407 to 744)	284 (199 to 404)	211 (151 to 295)	47.6 (34.4 to 65.8)
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	54.1 (36.4 to 80.5)	9999 (9999 to 9999)	39.9 (23.4 to 68.1)	9999 (9999 to 9999)
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	36.9 (21.5 to 63.6)	9999 (9999 to 9999)	45.9 (28.5 to 73.8)	9999 (9999 to 9999)

End point values	Group 9: MenACYW Conjugate Vaccine (3-5 Months)	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		

Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A (n=28,26,25,29,29,27,25,21,19,18)	82.6 (34.3 to 199)	1.71 (0.786 to 3.74)		
Serogroup C (n=28,26,25,29,29,27,25,21,19,18)	159 (112 to 227)	3.30 (1.58 to 6.89)		
Serogroup Y (n=28,0,25,0,29,0,25,0,19,0)	128 (91.6 to 179)	9999 (9999 to 9999)		
Serogroup W (n=28,0,25,0,29,0,25,0,19,0)	82.6 (55.1 to 124)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: All Groups: Percentage of Participants With rSBA Titers >=1:8 and >=1:128

End point title	All Groups: Percentage of Participants With rSBA Titers >=1:8 and >=1:128

End point description:

Seropositivity (rSBA titers >=1:8) and antibody responses of rSBA titers >=1:128 to meningococcal serogroups A, C, Y, and W for MenACYW conjugate vaccine and meningococcal serogroups A and C for MenAC conjugate vaccine were determined. Analysis was performed on the per-protocol analysis set which was the subset of FAS which included participants who received at least 1 dose of the study vaccine and had a valid post-vaccination serology result. Here, n=0 indicates that response to only serogroups A and C were determined for the comparators and not Y and W. Hence the corresponding data is reported as 9999 indicating 'not applicable'. SG: serogroup. Percentages are rounded off to the tenth decimal place.

End point type	Secondary

End point timeframe:

30 days after vaccination (Day 31 for Groups 1 to 6, Day 61 for Groups 7 and 8 and Day 91 for Groups 9 and 10)

End point values	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	26	25	29
Units: percentage of participants				
number (confidence interval 95%)				
SG A, >=1:8 (n=28,26,25,29,29,27,25,21,19,18)	100 (87.7 to 100)	84.6 (65.1 to 95.6)	100 (86.3 to 100)	100 (88.1 to 100)
SG A, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	96.4 (81.7 to 99.9)	50.0 (29.9 to 70.1)	96.0 (79.6 to 99.9)	93.1 (77.2 to 99.2)
SG C, >=1:8(n=28,26,25,29,29,27,25,21,19,	100 (87.7 to 100)	38.5 (20.2 to 59.4)	100 (86.3 to 100)	100 (88.1 to 100)
SG C, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	100 (87.7 to 100)	7.7 (0.9 to 25.1)	100 (86.3 to 100)	100 (88.1 to 100)
SG Y, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	96.4 (81.7 to 99.9)	9999 (9999 to 9999)	100 (86.3 to 100)	9999 (9999 to 9999)

SG Y, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	92.9 (76.5 to 99.1)	9999 (9999 to 9999)	96.0 (79.6 to 99.9)	9999 (9999 to 9999)
SG W, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	100 (87.7 to 100)	9999 (9999 to 9999)	96.0 (79.6 to 99.9)	9999 (9999 to 9999)
SG W, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	89.3 (71.8 to 97.7)	9999 (9999 to 9999)	72.0 (50.6 to 87.9)	9999 (9999 to 9999)

End point values	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	27	25	21
Units: percentage of participants				
number (confidence interval 95%)				
SG A, >=1:8 (n=28,26,25,29,29,27,25,21,19,18)	100 (88.1 to 100)	88.9 (70.8 to 97.6)	96.0 (79.6 to 99.9)	76.2 (52.8 to 91.8)
SG A, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	79.3 (60.3 to 92.0)	63.0 (42.4 to 80.6)	56.0 (34.9 to 75.6)	42.9 (21.8 to 66.0)
SG C, >=1:8(n=28,26,25,29,29,27,25,21,19,	100 (88.1 to 100)	100 (87.2 to 100)	100 (86.3 to 100)	100 (83.9 to 100)
SG C, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	100 (88.1 to 100)	88.9 (70.8 to 97.6)	84.0 (63.9 to 95.5)	14.3 (3.0 to 36.3)
SG Y, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	96.6 (82.2 to 99.9)	9999 (9999 to 9999)	92.0 (74.0 to 99.0)	9999 (9999 to 9999)
SG Y, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	34.5 (17.9 to 54.3)	9999 (9999 to 9999)	24.0 (9.4 to 45.1)	9999 (9999 to 9999)
SG W, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	93.1 (77.2 to 99.2)	9999 (9999 to 9999)	96.0 (79.6 to 99.9)	9999 (9999 to 9999)
SG W, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	27.6 (12.7 to 47.2)	9999 (9999 to 9999)	28.0 (12.1 to 49.4)	9999 (9999 to 9999)

End point values	Group 9: MenACYW Conjugate Vaccine (3-5 Months)	Group 10: Green Bamboo's MenAC Conjugate Vaccine (3-5		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	19	18		
Units: percentage of participants				
number (confidence interval 95%)				
SG A, >=1:8 (n=28,26,25,29,29,27,25,21,19,18)	94.7 (74.0 to 99.9)	11.1 (1.4 to 34.7)		
SG A, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	47.4 (24.4 to 71.1)	11.1 (1.4 to 34.7)		
SG C, >=1:8(n=28,26,25,29,29,27,25,21,19,	100 (82.4 to 100)	38.9 (17.3 to 64.3)		
SG C, >=1:128 (n=28,26,25,29,29,27,25,21,19,18)	84.2 (60.4 to 96.6)	0 (0 to 18.5)		
SG Y, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	100 (82.4 to 100)	9999 (9999 to 9999)		
SG Y, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	73.7 (48.8 to 90.9)	9999 (9999 to 9999)		

SG W, >=1:8 (n=28,0,25,0,29,0,25,0,19,0)	100 (82.4 to 100)	9999 (9999 to 9999)		
SG W, >=1:128 (n=28,0,25,0,29,0,25,0,19,0)	52.6 (28.9 to 75.6)	9999 (9999 to 9999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From date of first vaccination (Day 1) up to 6 months after the last study vaccination, approximately 180 days for Groups 1 to 6, 210 days for Groups 7, 8 and 240 days for Groups 9, 10

Adverse event reporting additional description:

Analysis was performed on the safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Group 1: MenACYW Conjugate Vaccine (7-17 Years)

Reporting group description:

Participants aged 7 to 17 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.

Reporting group title	Group 2: Green Bamboo’s MenAC Conjugate Vaccine (7-17 Years)

Reporting group description:

Participants aged 7 to 17 years received a single dose of 0.5 mL Green Bamboo’s MenAC conjugate vaccine IM injection on Day 1.

Reporting group title	Group 3: MenACYW Conjugate Vaccine (2-6 Years)

Reporting group description:

Participants aged 2 to 6 years received a single dose of 0.5 mL MenACYW conjugate vaccine IM injection on Day 1.

Reporting group title	Group 4: Royal’s MenAC Conjugate Vaccine (2-6 Years)

Reporting group description:

Participants aged 2 to 6 years received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1.

Reporting group title	Group 5: MenACYW Conjugate Vaccine (12-23 Months)

Reporting group description:

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

Reporting group title	Group 6: Royal’s MenAC Conjugate Vaccine (12-23 Months)

Reporting group description:

Participants aged 12 to 23 months received a single dose of 0.5 mL Royal’s MenAC conjugate vaccine IM injection on Day 1. An additional dose of Royal’s MenAC conjugate vaccine was offered by the Investigator to participants in Group 6 after the study procedure on the last visit of blood sampling to comply with product’s approved vaccination schedule. This second dose of Royal’s vaccine was not a part of the study assessment and was administered at least 31 days after the study vaccination.

Reporting group title	Group 7: MenACYW Conjugate Vaccine (6-11 Months)

Reporting group description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1 and 31.

Reporting group title	Group 8: Royal’s MenAC Conjugate Vaccine (6-11 Months)

Reporting group description:

Participants aged 6 to 11 months received 2 doses of 0.5 mL Royal’s MenAC conjugate vaccine IM injection each on Days 1 and 31.

Reporting group title	Group 9: MenACYW Conjugate Vaccine (3-5 Months)

Reporting group description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL MenACYW conjugate vaccine IM injection each on Days 1, 31 and 61.

Reporting group title	Group 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months)

Reporting group description:

Participants aged 3 to 5 months received 3 doses of 0.5 mL Green Bamboo's MenAC conjugate vaccine IM injection each on Days 1, 31 and 61.

Serious adverse events	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	4 / 30 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Incarcerated Inguinal Hernia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Functional Gastrointestinal Disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Intestinal Obstruction			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Complicated Appendicitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Febrile Infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea Infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Herpangina			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Herpes Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Pneumonia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection Bacterial			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Tonsillitis Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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 4: Royal's MenAC Conjugate Vaccine (2-6 Years)	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 30 (10.00%)	7 / 30 (23.33%)	8 / 30 (26.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blepharitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Incarcerated Inguinal Hernia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Functional Gastrointestinal Disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Intestinal Obstruction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Bronchitis			

subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	4 / 30 (13.33%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Diarrhoea Infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Herpangina			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Pharyngitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Influenza			
subjects affected / exposed	1 / 30 (3.33%)	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 30 (3.33%)	4 / 30 (13.33%)	4 / 30 (13.33%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (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
Tonsillitis Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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
Varicella			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (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 7: MenACYW Conjugate Vaccine	Group 8: Royal's MenAC Conjugate	Group 9: MenACYW Conjugate Vaccine

	(6-11 Months)	Vaccine (6-11 Months)	(3-5 Months)
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 30 (43.33%)	14 / 28 (50.00%)	15 / 30 (50.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	0 / 30 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Incarcerated Inguinal Hernia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Functional Gastrointestinal Disorder			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	0 / 30 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Asthma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	0 / 30 (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
Infections and infestations			
Appendicitis Perforated			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Bronchitis			
subjects affected / exposed	2 / 30 (6.67%)	4 / 28 (14.29%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated Appendicitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Diarrhoea Infectious			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal Infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Hand-Foot-And-Mouth Disease			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpangina			
subjects affected / exposed	0 / 30 (0.00%)	1 / 28 (3.57%)	3 / 30 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 30 (3.33%)	3 / 28 (10.71%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Pneumonia			
subjects affected / exposed	7 / 30 (23.33%)	6 / 28 (21.43%)	12 / 30 (40.00%)
occurrences causally related to treatment / all	0 / 8	0 / 6	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Tonsillitis Bacterial			
subjects affected / exposed	4 / 30 (13.33%)	1 / 28 (3.57%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	0 / 30 (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 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months)		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 30 (46.67%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Febrile Convulsion			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Incarcerated Inguinal Hernia				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Functional Gastrointestinal Disorder				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal Obstruction				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asthma				
subjects affected / exposed	1 / 30 (3.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Urticaria				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis Perforated				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	3 / 30 (10.00%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Complicated Appendicitis				

subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 30 (3.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Febrile Infection				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea Infectious				
subjects affected / exposed	1 / 30 (3.33%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Infection				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hand-Foot-And-Mouth Disease				
subjects affected / exposed	2 / 30 (6.67%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Herpangina				
subjects affected / exposed	2 / 30 (6.67%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Herpes Pharyngitis				
subjects affected / exposed	0 / 30 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				

subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	9 / 30 (30.00%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Upper Respiratory Tract Infection Bacterial			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis Bacterial			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicella			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Group 1: MenACYW Conjugate Vaccine (7-17 Years)	Group 2: Green Bamboo's MenAC Conjugate Vaccine (7-17 Years)	Group 3: MenACYW Conjugate Vaccine (2-6 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 30 (33.33%)	11 / 30 (36.67%)	14 / 30 (46.67%)
Investigations			
Myocardial Necrosis Marker Increased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
General disorders and administration site conditions			
Crying			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Injection Site Erythema			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	5 / 30 (16.67%)
occurrences (all)	3	3	5
Injection Site Pain			
subjects affected / exposed	7 / 30 (23.33%)	8 / 30 (26.67%)	6 / 30 (20.00%)
occurrences (all)	7	8	6
Injection Site Swelling			
subjects affected / exposed	2 / 30 (6.67%)	3 / 30 (10.00%)	3 / 30 (10.00%)
occurrences (all)	2	3	3
Malaise			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	2 / 30 (6.67%)
occurrences (all)	2	0	2
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	4 / 30 (13.33%)
occurrences (all)	1	0	4
Gastrointestinal disorders			

Functional Gastrointestinal Disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 30 (6.67%)	2 / 30 (6.67%)	6 / 30 (20.00%)
occurrences (all)	2	2	6
Rhinorrhoea			
subjects affected / exposed	3 / 30 (10.00%)	1 / 30 (3.33%)	0 / 30 (0.00%)
occurrences (all)	4	1	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	2 / 30 (6.67%)	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	2	1	2
Infections and infestations			
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 30 (0.00%)	1 / 30 (3.33%)	2 / 30 (6.67%)
occurrences (all)	0	1	3
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Group 4: Royal's MenAC Conjugate Vaccine (2-6 Years)	Group 5: MenACYW Conjugate Vaccine (12-23 Months)	Group 6: Royal's MenAC Conjugate Vaccine (12-23 Months)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 30 (33.33%)	15 / 30 (50.00%)	15 / 30 (50.00%)
Investigations			
Myocardial Necrosis Marker Increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Crying			
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)	2 / 30 (6.67%)
occurrences (all)	0	3	2
Injection Site Erythema			
subjects affected / exposed	2 / 30 (6.67%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Injection Site Pain			
subjects affected / exposed	3 / 30 (10.00%)	2 / 30 (6.67%)	1 / 30 (3.33%)
occurrences (all)	3	2	1
Injection Site Swelling			
subjects affected / exposed	3 / 30 (10.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Malaise			

subjects affected / exposed	1 / 30 (3.33%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)	6 / 30 (20.00%)	5 / 30 (16.67%)
occurrences (all)	1	6	6
Gastrointestinal disorders			
Functional Gastrointestinal Disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	3 / 30 (10.00%)	2 / 30 (6.67%)
occurrences (all)	0	3	2
Vomiting			
subjects affected / exposed	1 / 30 (3.33%)	3 / 30 (10.00%)	3 / 30 (10.00%)
occurrences (all)	1	3	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 30 (13.33%)	6 / 30 (20.00%)	3 / 30 (10.00%)
occurrences (all)	6	6	3
Rhinorrhoea			
subjects affected / exposed	3 / 30 (10.00%)	3 / 30 (10.00%)	5 / 30 (16.67%)
occurrences (all)	3	3	5
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	0	2	2
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Influenza			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 30 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	2 / 30 (6.67%)
occurrences (all)	0	2	2
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	0 / 30 (0.00%)	2 / 30 (6.67%)	3 / 30 (10.00%)
occurrences (all)	0	2	3

Non-serious adverse events	Group 7: MenACYW Conjugate Vaccine (6-11 Months)	Group 8: Royal's MenAC Conjugate Vaccine (6-11 Months)	Group 9: MenACYW Conjugate Vaccine (3-5 Months)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 30 (86.67%)	23 / 28 (82.14%)	28 / 30 (93.33%)
Investigations			
Myocardial Necrosis Marker Increased			
subjects affected / exposed	0 / 30 (0.00%)	2 / 28 (7.14%)	2 / 30 (6.67%)
occurrences (all)	0	2	2
Nervous system disorders			
Somnolence			
subjects affected / exposed	2 / 30 (6.67%)	0 / 28 (0.00%)	3 / 30 (10.00%)
occurrences (all)	2	0	3
Headache			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Crying			
subjects affected / exposed	4 / 30 (13.33%)	0 / 28 (0.00%)	7 / 30 (23.33%)
occurrences (all)	5	0	9
Injection Site Erythema			
subjects affected / exposed	2 / 30 (6.67%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences (all)	2	0	1
Injection Site Pain			

subjects affected / exposed	1 / 30 (3.33%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Injection Site Swelling			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	19 / 30 (63.33%)	11 / 28 (39.29%)	15 / 30 (50.00%)
occurrences (all)	31	12	22
Gastrointestinal disorders			
Functional Gastrointestinal Disorder			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	3 / 30 (10.00%)	0 / 28 (0.00%)	5 / 30 (16.67%)
occurrences (all)	3	0	7
Vomiting			
subjects affected / exposed	5 / 30 (16.67%)	3 / 28 (10.71%)	3 / 30 (10.00%)
occurrences (all)	5	3	3
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	10 / 30 (33.33%)	12 / 28 (42.86%)	16 / 30 (53.33%)
occurrences (all)	11	15	23
Rhinorrhoea			
subjects affected / exposed	10 / 30 (33.33%)	12 / 28 (42.86%)	10 / 30 (33.33%)
occurrences (all)	11	14	11
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 30 (3.33%)	0 / 28 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Psychiatric disorders			
Irritability			
subjects affected / exposed	2 / 30 (6.67%)	0 / 28 (0.00%)	5 / 30 (16.67%)
occurrences (all)	3	0	5

Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 30 (3.33%)	2 / 28 (7.14%)	0 / 30 (0.00%)
occurrences (all)	1	2	0
Nasopharyngitis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 30 (0.00%)	1 / 28 (3.57%)	4 / 30 (13.33%)
occurrences (all)	0	1	4
Metabolism and nutrition disorders			
Decreased Appetite			
subjects affected / exposed	4 / 30 (13.33%)	0 / 28 (0.00%)	3 / 30 (10.00%)
occurrences (all)	4	0	3

Non-serious adverse events	Group 10: Green Bamboo’s MenAC Conjugate Vaccine (3-5 Months)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 30 (90.00%)		
Investigations			
Myocardial Necrosis Marker Increased			
subjects affected / exposed	3 / 30 (10.00%)		
occurrences (all)	3		
Nervous system disorders			
Somnolence			
subjects affected / exposed	4 / 30 (13.33%)		
occurrences (all)	4		
Headache			
subjects affected / exposed	0 / 30 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

Crying subjects affected / exposed occurrences (all)	3 / 30 (10.00%) 4		
Injection Site Erythema subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Injection Site Pain subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Injection Site Swelling subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Malaise subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0		
Pyrexia subjects affected / exposed occurrences (all)	14 / 30 (46.67%) 22		
Gastrointestinal disorders Functional Gastrointestinal Disorder subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Diarrhoea subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Vomiting subjects affected / exposed occurrences (all)	4 / 30 (13.33%) 4		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	18 / 30 (60.00%) 27		
Rhinorrhoea subjects affected / exposed occurrences (all)	12 / 30 (40.00%) 13		
Skin and subcutaneous tissue disorders			

Rash subjects affected / exposed occurrences (all)	2 / 30 (6.67%) 2		
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	4 / 30 (13.33%) 5		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0		
Infections and infestations Influenza subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 30 (0.00%) 0 1 / 30 (3.33%) 1 3 / 30 (10.00%) 3		
Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	3 / 30 (10.00%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 January 2024	The main reason for this amendment was to add an interim analysis for Cohorts 1 and 2 (participants from 2 through 17 years of age).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported