Clinical trial results:
A Phase 3b, Open-Label Study to Evaluate the Safety and Immunogenicity of Nimenrix® in Healthy Infants, Given at 3 and 12 Months of Age

Summary

EudraCT number	2020-005059-19
Trial protocol	FI PL
Global end of trial date	09 September 2022

Results information

Result version number	v1
This version publication date	05 March 2023
First version publication date	05 March 2023

Trial information

Trial identification

Sponsor protocol code	C0921062

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04819113
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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?	
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	10 January 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Safety: To describe the safety of 2 doses of Nimenrix when administered in healthy infants at 3 and 12 months of age.
Immunogenicity: To describe the immune response for Neisseria meningitidis serogroups A, C, W-135, and Y induced by 2 doses of Nimenrix administered at 3 and 12 months of age.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 April 2021
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	Finland: 95
Country: Number of subjects enrolled	Poland: 26
Country: Number of subjects enrolled	Spain: 24
Worldwide total number of subjects	145
EEA total number of subjects	145

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)	145
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total of 153 subjects were screened, of which 4 were screen failures.149 subjects were enrolled and randomised in study of which 2 subjects did not receive any vaccination. 147 subjects received vaccination of which 2 subjects received at least 1 dose of vaccination but had no available safety information; hence, excluded from safety population.

Period 1

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

Arms

Arm title	Nimenrix

Arm description:

Subjects aged 3 months were administered a single dose of 0.5 millilitre (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1. Subjects received the second dose of Nimenrix (Vaccination 2) at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 0.5 mL of Nimenrix intramuscularly into the left thigh muscle at Visits 1 and 3.

Number of subjects in period 1	Nimenrix
Started	145
Completed	143
Not completed	2
Withdrawal by parent/guardian	2

Baseline characteristics

Reporting groups	
Reporting group title	Nimenrix
Reporting group description:	
Subjects aged 3 months were administered a single dose of 0.5 millilitre (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1. Subjects received the second dose of Nimenrix (Vaccination 2) at 12 months of age.	

Reporting group values	Nimenrix	Total	
Number of subjects	145	145	
Age Categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	145	145	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: days			
arithmetic mean	94.4		
standard deviation	± 6.09	-	
Gender Categorical Units: Subjects			
Female	76	76	
Male	69	69	
Race Units: Subjects			
Asian	1	1	
White	141	141	
Multiracial	2	2	
Not reported	1	1	
Ethnicity Units: Subjects			
Hispanic or Latino	26	26	
Non-Hispanic or non-Latino	119	119	

End points

End points reporting groups

Reporting group title	Nimenrix

Reporting group description:

Subjects aged 3 months were administered a single dose of 0.5 millilitre (mL) Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1. Subjects received the second dose of Nimenrix (Vaccination 2) at 12 months of age.

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2[1]

End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by the subject's parents/legal guardians in an electronic diary (e-diary). Redness and swelling were measured and recorded in measuring device units. 1 measuring device unit =0.5 centimeter (cm) and graded as mild: greater than (>)0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; and severe: >7.0 cm. Pain at injection site was graded as mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: limited limb movement. Exact 2-sided confidence interval (CI) was based on the Clopper and Pearson method. Safety population included all enrolled subjects who received at least 1 dose of investigational product (IP) and had safety data reported after vaccination. Here, 'Number of Subjects Analysed' (N)=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	142			
Units: Percentage of subjects				
number (confidence interval 95%)				
Pain at injection site: Mild	19.7 (13.5 to 27.2)			
Pain at injection site: Moderate	7.7 (3.9 to 13.4)			
Pain at injection site: Severe	0 (0.0 to 2.6)			
Redness: Mild	14.1 (8.8 to 20.9)			
Redness: Moderate	2.8 (0.8 to 7.1)			
Redness: Severe	0 (0.0 to 2.6)			
Swelling: Mild	4.9 (2.0 to 9.9)			
Swelling: Moderate	1.4 (0.2 to 5.0)			
Swelling: Severe	0 (0.0 to 2.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2[2]

End point description:

Systemic events included fever, decreased appetite, increased sleep and irritability were recorded in e-diary. Fever was defined as temperature greater than or equal to (>=) 38.0 degrees (deg) Celsius (C), categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C; decreased appetite graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed; increased sleep graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity; irritability graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Exact 2-sided CI was based on Clopper and Pearson method. Safety population: all enrolled subjects who received at least 1 dose of IP and had safety data reported after vaccination. N=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	142			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38.0 deg C to 38.4 deg C	6.3 (2.9 to 11.7)			
Fever: >38.4 deg C to 38.9 deg C	4.9 (2.0 to 9.9)			
Fever: >38.9 deg C to 40.0 deg C	3.5 (1.2 to 8.0)			
Fever: >40.0 deg C	0 (0.0 to 2.6)			
Decreased appetite: Mild	19.7 (13.5 to 27.2)			
Decreased appetite: Moderate	11.3 (6.6 to 17.7)			
Decreased appetite: Severe	1.4 (0.2 to 5.0)			
Increased sleep: Mild	38.0 (30.0 to 46.5)			
Increased sleep: Moderate	11.3 (6.6 to 17.7)			
Increased sleep: Severe	1.4 (0.2 to 5.0)			
Irritability: Mild	18.3 (12.3 to 25.7)			
Irritability: Moderate	42.3 (34.0 to 50.8)			
Irritability: Severe	2.8 (0.8 to 7.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Serious Adverse Events (SAEs) Within 30 Days After Vaccination 2

End point title	Percentage of Subjects With Serious Adverse Events (SAEs) Within 30 Days After Vaccination 2[3]

End point description:

An SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second doses of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3.

End point type	Primary

End point timeframe:

Within 30 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	143			
Units: Percentage of subjects				
number (confidence interval 95%)	1.4 (0.2 to 5.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Newly Diagnosed Chronic Medical Conditions (NDCMCs) Within 30 Days After Vaccination 2

End point title	Percentage of Subjects With Newly Diagnosed Chronic Medical Conditions (NDCMCs) Within 30 Days After Vaccination 2[4]

End point description:

An NDCMC was defined as a significant disease or medical condition, not previously identified, that is expected to be persistent or was otherwise long-lasting in its effects. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second doses of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3.

End point type	Primary

End point timeframe:

Within 30 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	143			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Adverse Events (AEs) Within 30 Days After Vaccination 2

End point title	Percentage of Subjects With Adverse Events (AEs) Within 30 Days After Vaccination 2[5]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second doses of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3.

End point type	Primary

End point timeframe:

Within 30 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	143			
Units: Percentage of subjects				
number (confidence interval 95%)	19.6 (13.4 to 27.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 2

End point title	Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 2[6]

End point description:

The use of antipyretic medication was recorded by the subject's parents/legal guardians in an e-diary for 7 days after vaccination. Exact 2-sided CI was based on the Clopper and Pearson method. Safety population included all enrolled subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here, 'Number of Subjects Analysed'= subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 days after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	142			
Units: Percentage of subjects				
number (confidence interval 95%)	55.6 (47.1 to 64.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 2

End point title	Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 2[7]

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after administration of the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 2 safety population included subjects who received the first and second doses of investigational product at Visit 1 and Visit 3 and for whom safety information was available from Visit 3.

End point type	Primary

End point timeframe:

Within 30 minutes after Vaccination 2

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	143			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titers >=1:8 for Each Serogroup, Neisseria Meningitidis Group A (MenA), MenC, MenW-135 and MenY at Baseline: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving Serum Bactericidal Assay Using Rabbit Complement (rSBA) Titers >=1:8 for Each Serogroup, Neisseria Meningitidis Group A (MenA), MenC, MenW-135 and MenY at Baseline: Post Dose 2 Evaluable Immunogenicity Population[8]

End point description:

Percentage of subjects achieving rSBA titer >=1:8 for each serogroup MenA, MenC, MenW-135 and MenY at baseline in subjects who received vaccinations 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. Post dose 2 (PD2) evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at visit (V) 1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135, and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

At baseline

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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[9]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[9] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 1: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 1: Post Dose 2 Evaluable Immunogenicity Population[10]

End point description:

Percentage of subjects achieving rSBA titer >=1:8 for each serogroup MenA, MenC, MenW-135 and MenY at 1 month after Vaccination 1 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month after Vaccination 1

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[11]			
Units: Percentage of Subjects				
number (confidence interval 95%)	(to)			

Notes:

[11] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population[12]

End point description:

Percentage of subjects achieving rSBA titer >=1:8 for each serogroup MenA, MenC, MenW-135 and MenY at Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Vaccination 2

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[13]			
Units: Percentage of Subjects				
number (confidence interval 95%)	(to)			

Notes:

[13] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup

MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population[14]

End point description:

Percentage of subjects achieving rSBA titer >=1:8 for each serogroup MenA, MenC, MenW-135 and MenY at 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 Month After Vaccination 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[15]			
Units: Percentage of Subjects				
number (confidence interval 95%)	(to)			

Notes:

[15] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline: Post Dose 2 Evaluable Immunogenicity Population

End point title	Geometric Mean Titers (GMTs) of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline: Post Dose 2 Evaluable Immunogenicity Population[16]

End point description:

GMTs of rSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at baseline in subjects who received Vaccination 1 and 2 were reported in this endpoint. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

At baseline

Notes:

[16] - 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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[17]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[17] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 1: Post Dose 2 Evaluable Immunogenicity Population

End point title	GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 1: Post Dose 2 Evaluable Immunogenicity Population[18]

End point description:

GMTs of rSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups 1 month after Vaccination 1 in subjects who received Vaccination 1 and 2 were reported in this endpoint. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after Vaccination 1

Notes:

[18] - 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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[19]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[19] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population[20]

End point description:

GMTs of rSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

At Vaccination 2

Notes:

[20] - 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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[21]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[21] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Primary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population[22]

End point description:

GMTs of rSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

1 month after Vaccination 2

Notes:

[22] - 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: Only descriptive summary statistics was planned for the analysis of this endpoint.

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[23]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[23] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1

End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by the subject's parents/legal guardians in an e-diary. Redness and swelling were measured and recorded in measuring device units. 1 measuring device unit =0.5 centimeter (cm) and graded as mild: >0.0 to 2.0 cm; moderate: >2.0 to 7.0 cm; and severe: >7.0 cm. Pain at injection site was graded as mild: hurts if gently touched; moderate: hurts if gently touched with crying; severe: limited limb movement. Exact 2-sided CI was based on the Clopper and Pearson method. Safety population included all enrolled subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Secondary

End point timeframe:

Within 7 days after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)				
Pain at injection site: Mild	13.8 (8.6 to 20.5)			
Pain at injection site: Moderate	2.8 (0.8 to 6.9)			
Pain at injection site: Severe	0 (0.0 to 2.5)			
Redness: Mild	6.2 (2.9 to 11.5)			
Redness: Moderate	1.4 (0.2 to 4.9)			
Redness: Severe	0 (0.0 to 2.5)			
Swelling: Mild	1.4 (0.2 to 4.9)			
Swelling: Moderate	1.4 (0.2 to 4.9)			
Swelling: Severe	0 (0.0 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1

End point title	Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1

End point description:

Systemic events included fever, decreased appetite, increased sleep and irritability were recorded in e-diary. Fever was defined as temperature >=38.0 deg C, categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C; decreased appetite graded as mild: decreased interest in eating, moderate: decreased oral intake and severe: refusal to feed; increased sleep graded as mild: increased or prolonged sleeping bouts, moderate: slightly subdued, interfered with daily activity and severe: disabling, not interested in usual daily activity; irritability graded as mild: easily consolable, moderate: required increased attention and severe: inconsolable, crying could not be comforted. Exact 2-sided CI was based on Clopper and Pearson method. Safety population included all enrolled subjects who received at least 1 dose of IP and had safety data reported after vaccination.

End point type	Secondary

End point timeframe:

Within 7 days after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38.0 deg C to 38.4 deg C	7.6 (3.8 to 13.2)			
Fever: >38.4 deg C to 38.9 deg C	2.1 (0.4 to 5.9)			
Fever: >38.9 deg C to 40.0 deg C	0 (0.0 to 2.5)			
Fever: >40.0 deg C	0 (0.0 to 2.5)			
Decreased appetite: Mild	15.2 (9.8 to 22.1)			
Decreased appetite: Moderate	8.3 (4.3 to 14.0)			
Decreased appetite: Severe	0 (0.0 to 2.5)			
Increased sleep: Mild	57.2 (48.8 to 65.4)			
Increased sleep: Moderate	7.6 (3.8 to 13.2)			
Increased sleep: Severe	1.4 (0.2 to 4.9)			
Irritability: Mild	27.6 (20.5 to 35.6)			
Irritability: Moderate	40.0 (32.0 to 48.5)			
Irritability: Severe	4.8 (2.0 to 9.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 1

End point title	Percentage of Subjects With Use of Antipyretic Medication Within 7 Days After Vaccination 1

End point description:

The use of antipyretic medication was recorded by the subject's parents/legal guardians in an e-diary for 7 days after vaccination. Exact 2-sided CI was based on the Clopper and Pearson method. Safety population included all enrolled subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Secondary

End point timeframe:

Within 7 days after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)	39.3 (31.3 to 47.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With AEs Within 30 Days After Vaccination 1

End point title	Percentage of Subjects With AEs Within 30 Days After Vaccination 1

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

End point type	Secondary

End point timeframe:

Within 30 days after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)	6.9 (3.4 to 12.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SAEs and NDCMCs: Within 30 Days After Vaccination 1, From 1 Month After Vaccination 1 to 9 Months After Vaccination 1, From Vaccination 1 to 9 Months After Vaccination 1

End point title	Percentage of Subjects With SAEs and NDCMCs: Within 30 Days After Vaccination 1, From 1 Month After Vaccination 1 to 9 Months After Vaccination 1, From Vaccination 1 to 9 Months After Vaccination 1

End point description:

An SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. An NDCMC was defined as a significant disease or medical condition, not previously identified, that is expected to be persistent or was otherwise long-lasting in its effects. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

End point type	Secondary

End point timeframe:

Within 30 days after Vaccination 1, from 1 month (M) after Vaccination 1 to 9 months after Vaccination 1 and from Vaccination 1 to 9 months after Vaccination (Vacc.) 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)				
SAE: Within 30 days after Vacc. 1	1.4 (0.2 to 4.9)			
SAE: From 1 M after Vacc. 1 to 9 M after Vacc. 1	4.1 (1.5 to 8.8)			
SAE: From Vacc. 1 to 9 M after Vacc. 1	5.5 (2.4 to 10.6)			
NDCMC: Within 30 days after Vacc. 1	0.0 (0.0 to 2.5)			
NDCMC:From 1 M after Vacc. 1 to 9 M after Vacc. 1	0.0 (0.0 to 2.5)			
NDCMC: From Vacc. 1 to 9 M after Vacc. 1	0.0 (0.0 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 1

End point title	Percentage of Subjects With Immediate AE Within 30 Minutes After Vaccination 1

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after administration of the investigational product. Exact 2-sided CI was based on the Clopper and Pearson method. Dose 1 safety population included subjects who received the first dose of investigational product at Visit 1 and for whom safety information was available from Visit 1 to prior to Visit 3.

End point type	Secondary

End point timeframe:

Within 30 minutes after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	145			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 2.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving rSBA titer >=1:8 for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. Post dose 1 (PD1) evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[24]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[24] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers >= 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving rSBA titer >= 1:128 for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[25]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[25] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titers >= 1:4 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titers >= 1:4 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable

	Immunogenicity Population

End point description:

Percentage of subjects achieving hSBA titers >= 1:4 for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[26]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[26] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point description:

GMTs of hSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. PD1 evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[27]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[27] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving hSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving hSBA titers >= 1:8 for each serogroup MenA, MenC, MenW-135 and MenY at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD1 evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[28]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[28] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers >= 1:4 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving hSBA Titers >= 1:4 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After

	Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving hSBA titers >= 1:4 for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed' = subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[29]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[29] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving hSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving hSBA Titers >= 1:8 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving hSBA titers >= 1:8 for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[30]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[30] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point title	GMTs of rSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline and 1 Month After Vaccination 1: Post Dose 1 Evaluable Immunogenicity Population

End point description:

GMTs of rSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at baseline and 1 month after Vaccination 1 in subjects who received Vaccination 1 were reported in this endpoint. PD1 evaluable immunogenicity population: subjects enrolled and eligible through V2; received vaccine at V1; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and month 1 (V2; 1 month after dose 1: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V2, received no prohibited vaccines/treatment and had no protocol deviations through V2. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline and 1 month after Vaccination 1

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[31]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[31] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Achieving rSBA Titers >= 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	Percentage of Subjects Achieving rSBA Titers >= 1:128 for Each Serogroup MenA, MenC, MenW-135 and MenY at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point description:

Percentage of subjects achieving rSBA Titers >= 1:128 for each serogroup MenA, MenC, MenW-135 and MenY at baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[32]			
Units: Percentage of subjects				
number (confidence interval 95%)	(to)			

Notes:

[32] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point title	GMTs of hSBA Titer for Each of MenA, MenC, MenW-135 and MenY Serogroups at Baseline, 1 Month After Vaccination 1, at Vaccination 2 and 1 Month After Vaccination 2: Post Dose 2 Evaluable Immunogenicity Population

End point description:

GMTs of hSBA titer for each of MenA, MenC, MenW-135 and MenY serogroups at baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2 in subjects who received Vaccination 1 and 2 were reported in this endpoint. PD2 evaluable immunogenicity population: subjects enrolled and eligible through 1 month after dose 2 of vaccination; received vaccine at V1 and V3; blood drawn for assay testing within time frames at month 0 (V1; before dose 1) and at 1 month after dose 2 (V4; 1 month after dose 2: window 28-42 days); had at least 1 valid, determinate MenA, MenC, MenW-135 and MenY assay result at V4, received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, 'Number of Subjects Analysed'=subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

At baseline, 1 month after Vaccination 1, at Vaccination 2 and 1 month after Vaccination 2

End point values	Nimenrix			
Subject group type	Reporting group			
Number of subjects analysed	0[33]			
Units: Titer				
geometric mean (confidence interval 95%)	(to)			

Notes:

[33] - Data for this endpoint was not summarised due to delay in serology from the external laboratory.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Systematic assessment(SA): local reactions/systemic events recorded within 7 days after Vaccination (V) 1 and 2; Non-SA: SAEs: Day 1 up to 42 days after V 2; other AEs: from Day 1 up to 42 days after V 1 and from Day of V 2 up to 42 days after V 2

Adverse event reporting additional description:

Same event may appear as both an AE and SAE. However, what is presented are distinct events. An event may be categorised as serious in one subject and as non-serious in another, or a subject may have experienced both a serious and non-serious event. Safety population was evaluated.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Nimenrix

Reporting group description:

Subjects aged 3 months were administered a single dose of 0.5 mL Nimenrix (Vaccination 1) intramuscularly into the left thigh muscle on Day 1. Subjects received the second dose of Nimenrix (Vaccination 2) at 12 months of age.

Serious adverse events	Nimenrix		
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 145 (6.90%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Food protein-induced enterocolitis syndrome			

subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Laryngitis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	1 / 145 (0.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	3 / 145 (2.07%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Nimenrix		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	139 / 145 (95.86%)		
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences (all)	2		
Nervous system disorders			
Hypersomnia (INCREASED SLEEP)			
alternative assessment type: Systematic			

subjects affected / exposed	115 / 145 (79.31%)		
occurrences (all)	168		
General disorders and administration site conditions			
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	51 / 145 (35.17%)		
occurrences (all)	63		
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	12 / 145 (8.28%)		
occurrences (all)	13		
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	31 / 145 (21.38%)		
occurrences (all)	35		
Pyrexia			
subjects affected / exposed	5 / 145 (3.45%)		
occurrences (all)	5		
Skin and subcutaneous tissue disorders			
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	32 / 145 (22.07%)		
occurrences (all)	35		
Psychiatric disorders			
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	119 / 145 (82.07%)		
occurrences (all)	195		
Infections and infestations			
Laryngitis			
subjects affected / exposed	4 / 145 (2.76%)		
occurrences (all)	4		
Hand-foot-and-mouth disease			
subjects affected / exposed	2 / 145 (1.38%)		
occurrences (all)	2		

Gastroenteritis subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2		
Conjunctivitis subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2		
Bronchiolitis subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2		
Viral infection subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 145 (4.83%) 9		
Respiratory tract infection subjects affected / exposed occurrences (all)	3 / 145 (2.07%) 3		
Otitis media subjects affected / exposed occurrences (all)	2 / 145 (1.38%) 2		
Nasopharyngitis subjects affected / exposed occurrences (all)	8 / 145 (5.52%) 8		
Metabolism and nutrition disorders Decreased appetite (DECREASED APPETITE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	65 / 145 (44.83%) 80		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Data for the serology endpoints were not summarised due to delay in serology from the external laboratory.

Notes: