Clinical trial results:
A Phase II, Randomized, Open Label, Controlled, Multicenter Study to Evaluate the Safety, Immunogenicity and Induction of Immunological Memory After Two or Three Doses of Novartis (Formerly Chiron) Meningococcal ACWY Conjugate Vaccine Administered to Healthy Infants at 2, 3, 4 or 2, 4, 6 Months of Age

Summary

EudraCT number	2004-000195-13
Trial protocol	GB
Global end of trial date	02 October 2006

Results information

Result version number	v1 (current)
This version publication date	04 November 2018
First version publication date	04 November 2018
Summary attachment (see zip file)	V59P5 results (V59P5 receipt.pdf)

Trial information

Trial identification

Sponsor protocol code	V59P5

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00262002
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccine and Diagnostics S.r.l
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure OFfice, Novartis Pharma AG, Novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000032-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	02 October 2006
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 October 2006
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Immunogenicity was measured as the percentage of subjects with human serum bactericidal assay (hSBA) titers ≥ 1:4 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W and Y, at the baseline and 1 month after primary vaccination by groups.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2004
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	United Kingdom: 316
Country: Number of subjects enrolled	Canada: 285
Worldwide total number of subjects	601
EEA total number of subjects	316

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)	601
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:

Participants were enrolled at two centers in Canada and one in UK.

Pre-assignment

Screening details:

The two selected countries provided data on different infant vaccination schedules (at 2 and 4 months of age; at 2, 3, and 4 months of age: and at 2, 4, and 6 months of age), and on different recommended concomitant vaccinations.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Data analyst[1]

Arms

Are arms mutually exclusive?	Yes
Arm title	UK234+ (MenACWY Ad+ at 2,3,4 m)

Arm description:

Three doses of MenACWY Ad+ vaccine were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Arm title	UK24+ (MenACWY Ad+ at 2,4 m)

Arm description:

Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Arm title	UKMenC (Menjugate at 2,4m)

Arm description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Arm type	Active comparator

Investigational medicinal product name	Menjugate C
Investigational medicinal product code	
Other name	Menomune
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Menjugate C vaccine was reconstituted before injection.

Arm title	CA246+ (MenACWY Ad+ at 2,4,6m)

Arm description:

Three doses of MenACWY Ad+ vaccine were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Arm title	CA24+ (MenACWY Ad+ at 2,4m)

Arm description:

Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Arm title	UK24- (MenACWY Ad- at 2,4m)

Arm description:

Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Ad- Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine without adjuvant was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Arm title	CA24- (MenACWY Ad- at 2,4m)

Arm description:

Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV,

HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Arm type	Experimental
Investigational medicinal product name	MenACWY Ad- Conjugate vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY Conjugate vaccine without adjuvant was obtained by extemporaneous mixing just before injection of the lyophilized MenA component to be resuspended with the MenCWY component.

Notes:

[1] - The roles blinded appear inconsistent with a simple blinded trial.

Justification: open-label trial but the people who analyzed the data were blinded.

Number of subjects in period 1	UK234+ (MenACWY Ad+ at 2,3,4 m)	UK24+ (MenACWY Ad+ at 2,4 m)	UKMenC (Menjugate at 2,4m)
Started	90	90	45
Completed	79	84	45
Not completed	11	6	0
Consent withdrawn by subject	4	2	-
Adverse event, non-fatal	2	1	-
Unable to classify	-	-	-
Lost to follow-up	2	-	-
Protocol deviation	3	2	-
Inapropriate enrollment	-	1	-

Number of subjects in period 1	CA246+ (MenACWY Ad+ at 2,4,6m)	CA24+ (MenACWY Ad+ at 2,4m)	UK24- (MenACWY Ad- at 2,4m)
Started	98	98	90
Completed	93	91	83
Not completed	5	7	7
Consent withdrawn by subject	1	2	2
Adverse event, non-fatal	-	-	1
Unable to classify	-	-	-
Lost to follow-up	2	-	1
Protocol deviation	2	5	3
Inapropriate enrollment	-	-	-

Number of subjects in period 1	CA24- (MenACWY Ad- at 2,4m)
Started	90
Completed	84
Not completed	6
Consent withdrawn by subject	2
Adverse event, non-fatal	-
Unable to classify	2

Lost to follow-up	-
Protocol deviation	2
Inapropriate enrollment	-

Baseline characteristics

Reporting groups	
Reporting group title	UK234+ (MenACWY Ad+ at 2,3,4 m)
Reporting group description:	
Three doses of MenACWY Ad+ vaccine were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.	
Reporting group title	UK24+ (MenACWY Ad+ at 2,4 m)
Reporting group description:	
Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.	
Reporting group title	UKMenC (Menjugate at 2,4m)
Reporting group description:	
Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.	
Reporting group title	CA246+ (MenACWY Ad+ at 2,4,6m)
Reporting group description:	
Three doses of MenACWY Ad+ vaccine were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.	
Reporting group title	CA24+ (MenACWY Ad+ at 2,4m)
Reporting group description:	
Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.	
Reporting group title	UK24- (MenACWY Ad- at 2,4m)
Reporting group description:	
Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.	
Reporting group title	CA24- (MenACWY Ad- at 2,4m)
Reporting group description:	
Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.	

Reporting group values	UK234+ (MenACWY Ad+ at 2,3,4 m)	UK24+ (MenACWY Ad+ at 2,4 m)	UKMenC (Menjugate at 2,4m)
Number of subjects	90	90	45
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	90	90	45
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0

85 years and over	0	0	0

Age Continuous			
Units: days			
arithmetic mean	62.1	61.3	62.6
standard deviation	± 5.4	± 5.0	± 6.5
Gender, Male/Female			
Units: Subjects			
Female	44	41	26
Male	46	49	19

Reporting group values	CA246+ (MenACWY Ad+ at 2,4,6m)	CA24+ (MenACWY Ad+ at 2,4m)	UK24- (MenACWY Ad- at 2,4m)
Number of subjects	98	98	90
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	98	98	90
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: days			
arithmetic mean	65.6	65.8	64.1
standard deviation	± 6.9	± 6.9	± 5.5
Gender, Male/Female			
Units: Subjects			
Female	52	49	48
Male	46	49	42

Reporting group values	CA24- (MenACWY Ad- at 2,4m)	Total	
Number of subjects	90	601	
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)	90	601	
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	69.4		
standard deviation	± 10.0	-	
Gender, Male/Female Units: Subjects			
Female	44	304	
Male	46	297	

End points

End points reporting groups

Reporting group title	UK234+ (MenACWY Ad+ at 2,3,4 m)

Reporting group description:

Three doses of MenACWY Ad+ vaccine were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Reporting group title	UK24+ (MenACWY Ad+ at 2,4 m)

Reporting group description:

Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Reporting group title	UKMenC (Menjugate at 2,4m)

Reporting group description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Reporting group title	CA246+ (MenACWY Ad+ at 2,4,6m)

Reporting group description:

Three doses of MenACWY Ad+ vaccine were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Reporting group title	CA24+ (MenACWY Ad+ at 2,4m)

Reporting group description:

Two doses of MenACWY Ad+ vaccine were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Reporting group title	UK24- (MenACWY Ad- at 2,4m)

Reporting group description:

Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Reporting group title	CA24- (MenACWY Ad- at 2,4m)

Reporting group description:

Two doses of MenACWY Ad- vaccine were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant vaccine were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given

at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose (one fifth) of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose (one fifth) of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UKMenC (Menjugate 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	UK24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose (of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UKMenC (Menjugate at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2,4,6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4,6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available)

at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was to be given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)

Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	UK24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if

available) at 12 months of age.

Subject analysis set title	UKMenC (Menjugate at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was given at 12 months of age.

Subject analysis set title	UK24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	UKMenC (Menjugate at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of Menjugate were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was given at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine without adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m) - No Treatment
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Three doses of MenACWY conjugate vaccine with adjuvant were given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA246+ (MenACWY Ad+ at 2, 4, 6 m) - PS
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m) - ACWY
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24+ (MenACWY Ad+ at 2, 4 m) - PS
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	UK24- (MenACWY Ad- at 2, 4 m)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was given at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m) - ACWY
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose (one fifth) of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Subject analysis set title	CA24- (MenACWY Ad- at 2, 4 m) - PS
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Two doses of MenACWY conjugate vaccine with adjuvant were given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age. One dose of MenACWY Ad- vaccine or one reduced dose of MenACWY PS vaccine was given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Primary: Percentages of Subjects With hSBA Titers ≥ 1:4 Against N. Meningitidis Serogroups A, C, W, and Y Following 3 Doses of MenACWY Ad+ Vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 Against N. Meningitidis Serogroups A, C, W, and Y Following 3 Doses of MenACWY Ad+ Vaccine[1]

End point description:

Immunogenicity was measured as the percentage of subjects with human serum bactericidal assay (hSBA) titers ≥ 1:4 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W and Y, at the baseline and 1 month after primary vaccination by groups.

End point type	Primary

End point timeframe:

Baseline and at 1 month after the 3 dose primary vaccination series

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: descriptive statistics.

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	81	87		
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A - baseline (n=69,80)|	6 (2 to 14)	0 (0 to 5)		
Ser A - 1 month after primary vacc (n=69,80)|	93 (84 to 98)	81 (71 to 89)		
Ser C - baseline (n=79,86)|	18 (10 to 28)	15 (8 to 24)		
Ser C - 1 month after primary vacc (n=79,86)|	96 (89 to 99)	98 (92 to 100)		
Ser W - baseline (n=69,78)|	54 (41 to 66)	31 (21 to 42)		
Ser W - 1 month after primary vacc (n=69,78)|	97 (90 to 100)	99 (93 to 100)		
Ser Y - baseline|	21 (13 to 31)	17 (10 to 27)		
Ser Y - 1 month after primary vacc|	94 (86 to 98)	98 (92 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:8 Against N. Meningitidis Serogroups A, C, W, and Y Following 3 doses of MenACWY Ad+ conjugate vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:8 Against N. Meningitidis Serogroups A, C, W, and Y Following 3 doses of MenACWY Ad+ conjugate vaccine

End point description:

Immunogenicity was measured by percentages of subjects With hSBA titers ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W and Y, at baseline and 1 month after primary vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after the 3 dose primary vaccination series

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	81	87		
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A - baseline (n=69,80)|	4 (1 to 12)	0 (0 to 5)		
Ser A - 1 month after primary vacc (n=69,80)|	88 (78 to 95)	76 (65 to 85)		
Ser C - baseline (n=79,86)|	9 (4 to 17)	5 (1 to 11)		
Ser C - 1 month after primary vacc (n=79,86)|	92 (84 to 97)	98 (92 to 100)		
Ser W - baseline (n=69,78)|	46 (34 to 59)	28 (19 to 40)		
Ser W - 1 month after primary vacc (n=69,78)|	88 (78 to 95)	96 (89 to 99)		
Ser Y - baseline|	14 (7 to 23)	11 (6 to 20)		
Ser Y - 1 month after primary vaccination|	93 (85 to 97)	89 (80 to 94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMTs) Following 3 Doses of MenACWY Ad+ Conjugate Vaccine

End point title	Geometric Mean hSBA Titers (GMTs) Following 3 Doses of MenACWY Ad+ Conjugate Vaccine

End point description:

Immunogenicity was measured as hSBA GMTs and associated 95% CI, against N meningitis serogroups A, C, W, and Y, at the baseline and 1 month after primary vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after the 3 dose primary vaccination series

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	81	87		
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - baseline (n=69,80)|	2.2 (2.04 to 2.38)	2 (1.86 to 2.15)		

Ser A - 1 month after primary vacc (n=69,80)|	53 (38 to 74)	21 (15 to 29)		
Ser C - baseline (n=79,86)|	2.79 (2.36 to 3.31)	2.64 (2.25 to 3.11)		
Ser C - 1 month after primary vacc (n=79,86)|	79 (56 to 112)	124 (89 to 172)		
Ser W - baseline (n=69,78)|	5.76 (4.39 to 7.57)	4.03 (3.12 to 5.21)		
Ser W - 1 month after primary vacc (n=69,78)|	65 (46 to 92)	73 (53 to 102)		
Ser Y - baseline|	2.72 (2.34 to 3.17)	2.64 (2.28 to 3.05)		
Ser Y - 1 month after primary vacc|	56 (41 to 77)	2.64 (2.28 to 3.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 Against N. Meningitidis Serogroups A, C, W, and Y Following 2 doses of Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 Against N. Meningitidis Serogroups A, C, W, and Y Following 2 doses of Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines

End point description:

Immunogenicity was measured as the percentages of subjects With hSBA titers ≥ 1:4 and ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y, at Baseline and 1 month after second vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after second vaccination

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	CA24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	77	79	79	85
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4, baseline (N=68,79,78,83)	4 (1 to 12)	3 (0 to 9)	3 (0 to 9)	4 (1 to 10)
Ser A-hSBA≥1:4, 1m after 2nd vac(N=68,79,78,83)	60 (48 to 72)	66 (54 to 76)	50 (38 to 62)	57 (45 to 67)
Ser A-hSBA≥1:8, baseline (N=68,79,78,83)	3 (0 to 10)	1 (0.032 to 7)	0 (0 to 5)	1 (0.03 to 7)
Ser A-hSBA≥1:8,1m after 2nd vac(N=68,79,78,83)	54 (42 to 67)	58 (47 to 69)	44 (32 to 55)	49 (38 to 61)
Ser C-hSBA≥1:4,baseline (N=77,74,79,85)	13 (6 to 23)	15 (8 to 25)	20 (12 to 31)	20 (12 to 30)
Ser C-hSBA ≥1:4,1m after 2nd vac(N=77,74,79,85)	84 (74 to 92)	91 (81 to 96)	86 (76 to 93)	93 (85 to 97)

Ser C-hSBA≥1:8,baseline (N=77,74,79,85)	9 (4 to 18)	15 (8 to 25)	5 (1 to 12)	11 (5 to 19)
Ser C-hSBA≥1:8,1m after 2nd vac(N=77,74,79,85)	83 (73 to 91)	85 (75 to 92)	82 (72 to 90)	89 (81 to 95)
Ser W-hSB≥1:4, baseline (N=73,74,72,75)	45 (34 to 57)	24 (15 to 36)	43 (31 to 55)	19 (11 to 29)
Ser W-hSBA≥1:4,1m after 2nd vac(N=73,74,72,75)	92 (83 to 97)	91 (81 to 96)	82 (71 to 90)	95 (87 to 99)
Ser W-hSBA≥1:8, baseline (N=73,74,72,75)	37 (26 to 49)	19 (11 to 30)	36 (25 to 48)	16 (9 to 26)
Ser W-hSBA≥1:8,1m after 2nd vac(N=73,74,72,75)	84 (73 to 91)	85 (75 to 92)	75 (63 to 84)	92 (83 to 97)
Ser Y-hSBA≥1:4, baseline (N=76,74,77,85)	18 (10 to 29)	9 (4 to 19)	35 (25 to 47)	18 (10 to 27)
Ser Y-hSBA ≥1:4,1m after 2nd vac(N=76,74,77,85)	84 (74 to 92)	86 (77 to 93)	74 (63 to 83)	91 (82 to 96)
Ser Y-hSBA≥1:8, baseline (N=76,74,77,85)	7 (2 to 15)	4 (1 to 11)	16 (8 to 26)	11 (5 to 19)
Ser Y-hSBA≥1:8,1m after 2nd vacc(N=76,74,77,85)	76 (65 to 85)	80 (69 to 88)	70 (59 to 80)	86 (77 to 92)

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA titer (GMTs) following 2 doses of MenACWY Ad+ and MenACWY Ad- conjugate vaccines

End point title	Geometric Mean hSBA titer (GMTs) following 2 doses of MenACWY Ad+ and MenACWY Ad- conjugate vaccines

End point description:

Immunogenicity was measured as hSBA GMTs and associated 95% CI against N. Meningitidis serogroups A, C, W, and Y at baseline and 1 month after second vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after second vaccination

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	CA24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	77	79	79	85
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - baseline (n=68,79,78,83)|	2.17 (2.01 to 2.35)	2.07 (1.93 to 2.23)	2.05 (1.91 to 2.21)	2.08 (1.94 to 2.23)
Ser A - 1 month after 2nd vacc (n=68,79,78,83)|	12 (8.36 to 16)	11 (7.91 to 15)	7.3 (5.31 to 10)	7.16 (5.26 to 9.73)
Ser C - baseline (n=77,74,79,85)|	2.54 (2.14 to 3.02)	2.77 (2.33 to 3.31)	2.48 (2.09 to 2.94)	2.87 (2.44 to 3.39)
Ser C - 1 month after 2nd vacc (n=77,74,79,85)|	52 (37 to 74)	55 (38 to 79)	40 (28 to 57)	69 (49 to 96)

Ser W - baseline (n=73,74,79,75)|	5.33 (4.09 to 6.94)	3.6 (2.77 to 4.69)	5.14 (3.94 to 6.71)	3.02 (2.33 to 3.93)
Ser W - 1 month after 2nd vacc (n=73,74,79,75)|	48 (34 to 67)	44 (31 to 61)	29 (20 to 40)	69 (50 to 96)
Ser Y - baseline (n=76,74,77,85)|	2.56 (2.19 to 2.99)	2.27 (1.94 to 2.66)	3.39 (2.9 to 3.96)	2.76 (2.38 to 3.21)
Ser Y - 1 month after 2nd vacc (n=76,74,77,85)|	26 (19 to 37)	27 (19 to 38)	21 (15 to 29)	41 (30 to 56)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 against N. Meningitidis serogroups A, C, W & Y after a Booster Dose of MenACWY Ad+ or Ad- Vaccine in a Subgroup of Subjects Following 2 or 3 Doses or MenACWY Ad+ or 2 Doses of MenACWY Ad- Vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 against N. Meningitidis serogroups A, C, W & Y after a Booster Dose of MenACWY Ad+ or Ad- Vaccine in a Subgroup of Subjects Following 2 or 3 Doses or MenACWY Ad+ or 2 Doses of MenACWY Ad- Vaccine

End point description:

Immunogenicity was measured as the percentages of subjects with hSBA ≥ 1:4 or ≥ 1:8 and associated 95% CI, against N. Meningitidis serogroups A, C, W, and Y, at 12 months of age and 1 month after booster by groups.

End point type	Secondary

End point timeframe:

at 12 months of age and 1 month after booster vaccination

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	63	65	40
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4,at 12m of age(n=64,61,62,39,38)	8 (3 to 17)	7 (2 to 16)	21 (12 to 33)	5 (1 to 17)
Ser A-hSBA≥1:4, 1m after booster vac	86 (75 to 93)	79 (66 to 88)	94 (84 to 98)	92 (79 to 98)
Ser A-hSBA ≥1:8, at 12 m of age	5 (1 to 13)	5 (1 to 14)	13 (6 to 24)	3 (0.065 to 13)
Ser A-hSBA ≥1:8, 1 m after booster vaccination	83 (71 to 91)	77 (65 to 87)	92 (82 to 97)	90 (76 to 97)
Ser C-hSBA ≥1:4, at 12 m of age(n=67,63,65,40,40)	40 (28 to 53)	33 (22 to 46)	60 (47 to 72)	48 (32 to 64)
Ser C-hSBA≥1:4,1 m after booster(n=57,63,65,40,40)	96 (87 to 99)	94 (85 to 98)	98 (92 to 100)	98 (87 to 100)
Ser C-hSBA≥1:8, at 12 m of age(n=67,40,65,40,40)	34 (23 to 47)	27 (17 to 40)	52 (40 to 65)	35 (21 to 52)
Ser C-hSBA≥1:8, 1m after booster(n=67,63,65,40,40)	96 (87 to 99)	94 (85 to 98)	98 (92 to 100)	95 (83 to 99)

Ser W-hSBA≥1:4, at 12 m of age(n=57,41,57,35,35)	56 (42 to 69)	54 (37 to 69)	81 (68 to 90)	74 (57 to 88)
Ser W-hSBA≥1:4, 1m after booster vaccination	100 (94 to 100)	100 (91 to 100)	100 (94 to 100)	100 (90 to 100)
Ser W-hSBA≥1:8, at 12 m of age(n=57,41,40,35,35)	47 (34 to 61)	41 (26 to 58)	68 (55 to 80)	49 (31 to 66)
Ser W-hSBA≥1:8,1m after booster(n=57,41,57,35,35)	100 (94 to 100)	100 (91 to 100)	100 (94 to 100)	100 (90 to 100)
Ser Y -hSBA≥1:4, at 12m of age(n=66,63,65,40,38)|	52 (39 to 64)	52 (39 to 65)	86 (75 to 93)	65 (48 to 79)
Ser Y-hSBA≥1:4, 1 m after booster vaccination	100 (95 to 100)	100 (94 to 100)	100 (94 to 100)	100 (91 to 100)
Ser Y-hSBA ≥1:8, at 12 months of age	39 (28 to 52)	41 (29 to 54)	72 (60 to 83)	45 (29 to 62)
Ser Y-hSBA≥1:8, 1 m after booster vaccination	100 (95 to 100)	100 (94 to 100)	100 (94 to 100)	100 (91 to 100)

End point values	CA24-(MenACWY Ad-at 2, 4 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	40			
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4,at 12m of age(n=64,61,62,39,38)	3 (0.067 to 14)			
Ser A-hSBA≥1:4, 1m after booster vac	95 (82 to 99)			
Ser A-hSBA ≥1:8, at 12 m of age	3 (0.067 to 14)			
Ser A-hSBA ≥1:8, 1 m after booster vaccination	92 (79 to 98)			
Ser C-hSBA ≥1:4, at 12 m of age(n=67,63,65,40,40)	33 (19 to 49)			
Ser C-hSBA≥1:4,1 m after booster(n=57,63,65,40,40)	100 (91 to 100)			
Ser C-hSBA≥1:8, at 12 m of age(n=67,40,65,40,40)	25 (13 to 41)			
Ser C-hSBA≥1:8, 1m after booster(n=67,63,65,40,40)	100 (91 to 100)			
Ser W-hSBA≥1:4, at 12 m of age(n=57,41,57,35,35)	69 (51 to 83)			
Ser W-hSBA≥1:4, 1m after booster vaccination	100 (90 to 100)			
Ser W-hSBA≥1:8, at 12 m of age(n=57,41,40,35,35)	54 (37 to 71)			
Ser W-hSBA≥1:8,1m after booster(n=57,41,57,35,35)	100 (90 to 100)			
Ser Y -hSBA≥1:4, at 12m of age(n=66,63,65,40,38)|	63 (46 to 78)			
Ser Y-hSBA≥1:4, 1 m after booster vaccination	100 (91 to 100)			
Ser Y-hSBA ≥1:8, at 12 months of age	53 (36 to 69)			
Ser Y-hSBA≥1:8, 1 m after booster vaccination	100 (91 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMT) after a Booster Dose of MenACWY Ad+ or Ad- Vaccine Conjugate in a Subgroup of Subjects Following Either 2 or 3 Doses of MenACWY Ad+ Vaccine or 2 Doses of MenACWY Ad- Conjugate Vaccines

End point title	Geometric Mean hSBA Titers (GMT) after a Booster Dose of MenACWY Ad+ or Ad- Vaccine Conjugate in a Subgroup of Subjects Following Either 2 or 3 Doses of MenACWY Ad+ Vaccine or 2 Doses of MenACWY Ad- Conjugate Vaccines

End point description:

Immunogenicity was measured as GMT and associated 95% CI against N. Meningitidis serogroups A, C, W, and Y, at 12 months of age and 1 month after booster by group.

End point type	Secondary

End point timeframe:

at 12 months of age and 1 month after booster vaccination

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	67	63	65	40
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - at 12 months of age (n=64,61,62,39,38)|	2.31 (2 to 2.66)	2.22 (1.92 to 2.57)	2.97 (2.57 to 3.44)	2.07 (1.65 to 2.6)
Ser A - 1 month after booster (n=64,61,62,39,38)|	47 (31 to 72)	30 (19 to 47)	134 (87 to 207)	59 (38 to 93)
Ser C - at 12 months of age(n=67,63,65,40,40)|	5.18 (3.83 to 7.02)	3.94 (2.88 to 5.39)	7.94 (5.84 to 11)	4.07 (2.73 to 6.06)
Ser C - 1 month after booster(n=67,63,65,40,40)|	236 (159 to 349)	129 (86 to 194)	429 (288 to 639)	258 (56 to 426)
Ser W - at 12 months of age(n=57,41,57,35,35)|	8.1 (5.76 to 11)	6.49 (4.34 to 9.7)	16 (11 to 23)	11 (7.04 to 17)
Ser W - 1 month after booster (n=57,41,57,35,35)|	503 (347 to 732)	311 (200 to 485)	792 (544 to 1154)	402 (236 to 684)
Ser Y - at 12 months of age (n=66,63,65,40,38)|	6.65 (4.88 to 9.06)	6.83 (4.98 to 9.37)	19 (14 to 26)	7.63 (5 to 12)
Ser Y- 1 month after booster(n=66,63,65,40,38)|	508 (358 to 723)	438 (305 to 628)	1395 (979 to 1989)	527 (322 to 862)

End point values	CA24+ (MenACWY Ad+ at 2, 4m)			
Subject group type	Subject analysis set			
Number of subjects analysed	40			
Units: titers				
geometric mean (confidence interval 95%)				

Ser A - at 12 months of age (n=64,61,62,39,38)|	2.18 (1.74 to 2.73)			
Ser A - 1 month after booster (n=64,61,62,39,38)|	67 (43 to 106)			
Ser C - at 12 months of age(n=67,63,65,40,40)|	4.64 (3.11 to 6.91)			
Ser C - 1 month after booster(n=67,63,65,40,40)|	216 (130 to 356)			
Ser W - at 12 months of age(n=57,41,57,35,35)|	8.84 (5.63 to 14)			
Ser W - 1 month after booster (n=57,41,57,35,35)|	381 (224 to 650)			
Ser Y - at 12 months of age (n=66,63,65,40,38)|	7.99 (5.29 to 12)			
Ser Y- 1 month after booster(n=66,63,65,40,38)|	308 (191 to 499)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 and ≥ 1:8 against N. Meningitidis serogroups A, C, W and Y following 2 doses of Novartis MenACWY Ad+ Vaccine, Novartis MenACWY Ad- vaccine or Novartis Menjugate vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 and ≥ 1:8 against N. Meningitidis serogroups A, C, W and Y following 2 doses of Novartis MenACWY Ad+ Vaccine, Novartis MenACWY Ad- vaccine or Novartis Menjugate vaccine

End point description:

The persistence of immune response was measured as the percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 against N. Meningitidis serogroups A, C, W, and Y at 12 months of age by groups.

End point type	Secondary

End point timeframe:

at 12 months of age

End point values	UKMenC (Menjugate 2, 4 m)	UK24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	38	69	66	77
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4, at 12m of age(n=36,62,65,77,78)	0 (0 to 10)	8 (3 to 18)	6 (2 to 15)	8 (3 to 16)
Ser A-hSBA≥1:8, at 12m of age(n=36,62,65,77,78)	0 (0 to 10)	5 (1 to 13)	5 (1 to 13)	5 (1 to 13)
Ser C-hSBA≥1:4, at 12m of age(n=38,69,69,73,81)	89 (75 to 97)	41 (29 to 53)	32 (21 to 44)	48 (36 to 60)
Ser C-hSBA≥1:8, at 12m of age(n=38,69,69,73,81)	87 (72 to 96)	33 (22 to 46)	26 (16 to 38)	40 (28 to 52)
Ser W-hSBA≥1:4, at 12m of age(n=34,62,42,69,69)	9 (2 to 24)	58 (45 to 70)	57 (41 to 72)	64 (51 to 75)

Ser W-hSBA≥1:8, at 12m of age(n=34,62,42,69,69)	6 (1 to 20)	48 (35 to 61)	45 (30 to 61)	52 (40 to 64)
Ser Y-hSBA≥1:4, at 12m of age(n=38,69,66,73,79)	5 (1 to 18)	51 (38 to 63)	56 (43 to 68)	60 (48 to 72)
Ser Y-hSBA≥1:8, at 12m of age(n=38,69,66,73,79)	3 (0.067 to 14)	42 (30 to 55)	45 (33 to 58)	51 (39 to 63)

End point values	CA24-(MenACWY Ad- at 2, 4 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	81			
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4, at 12m of age(n=36,62,65,77,78)	5 (1 to 13)			
Ser A-hSBA≥1:8, at 12m of age(n=36,62,65,77,78)	4 (1 to 11)			
Ser C-hSBA≥1:4, at 12m of age(n=38,69,69,73,81)	35 (24 to 46)			
Ser C-hSBA≥1:8, at 12m of age(n=38,69,69,73,81)	30 (20 to 41)			
Ser W-hSBA≥1:4, at 12m of age(n=34,62,42,69,69)	75 (64 to 85)			
Ser W-hSBA≥1:8, at 12m of age(n=34,62,42,69,69)	61 (48 to 72)			
Ser Y-hSBA≥1:4, at 12m of age(n=38,69,66,73,79)	59 (48 to 70)			
Ser Y-hSBA≥1:8, at 12m of age(n=38,69,66,73,79)	46 (34 to 57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMTs) after 2 doses of Novartis MenACWY Ad+ Vaccines, Novartis MenACWY Ad- Vaccine, or Novartis Menjugate vaccine.

End point title	Geometric Mean hSBA Titers (GMTs) after 2 doses of Novartis MenACWY Ad+ Vaccines, Novartis MenACWY Ad- Vaccine, or Novartis Menjugate vaccine.

End point description:

The persistence of immune response as measured by hSBA GMT and associated 95% CI against N. Meningitidis serogroups A, C, W, and Y, at 12 months of age by groups.

End point type	Secondary

End point timeframe:

at 12 months of age

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24+ (MenACWY Ad+ at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	69	66	77	81
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - at 12 months of age (n=36,62,65,77,78)|	2.32 (1.97 to 2.73)	2.2 (1.88 to 2.58)	2.29 (1.98 to 2.65)	2.18 (1.89 to 2.52)
Ser C - at 12 months of age (n=36,69,69,73,82)|	5.04 (3.73 to 6.81)	3.85 (2.85 to 5.21)	5.43 (4.05 to 7.27)	4.42 (3.35 to 5.84)
Ser W - at 12 months of age (n=34,62,42,69,69)|	8.38 (6.03 to 12)	7.02 (4.71 to 10)	8.15 (5.97 to 11)	12 (8.81 to 16)
Ser Y - at 12 months of age (n=38,69,66,73,79)|	6.72 (4.92 to 9.18)	7.64 (5.55 to 11)	7.84 (5.79 to 11)	7.12 (5.32 to 9.54)

End point values	UKMenC (Menjugate at 2, 4 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	38			
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - at 12 months of age (n=36,62,65,77,78)|	2 (1.62 to 2.48)			
Ser C - at 12 months of age (n=36,69,69,73,82)|	27 (18 to 40)			
Ser W - at 12 months of age (n=34,62,42,69,69)|	2.42 (1.55 to 3.78)			
Ser Y - at 12 months of age (n=38,69,66,73,79)|	2.15 (1.41 to 3.28)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 and ≥ 1:8 Against N. Meningitidis Serogroup A, C, W and Y following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 and ≥ 1:8 Against N. Meningitidis Serogroup A, C, W and Y following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point description:

The persistence of immune response as measured by percentages of subjects with hSBA≥ 1:4 and hSBA ≥ 1:8 and associated 95% CI, against N. Meningitidis serogroups A, C, W, and Y, at 12 months by groups.

End point type	Secondary

End point timeframe:

at 12 months of age

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	71	86		
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A - hSBA ≥1:4, at 12 months of age (n=58,79)|	21 (11 to 33)	35 (25 to 47)		
Ser A - hSBA ≥1:8, at 12 months of age(n=58,79)|	16 (7 to 27)	29 (19 to 40)		
Ser C - hSBA ≥1:4, at 12 months of age(n=70,84)|	59 (46 to 70)	75 (64 to 84)		
Ser C - hSBA ≥1:8, at 12 months of age(n=70,84)|	47 (35 to 59)	68 (57 to 78)		
Ser W - hSBA ≥1:4, at 12 months of age(n=58,75)|	78 (65 to 87)	89 (80 to 95)		
Ser W - hSBA ≥1:8, at 12 months of age(n=58,75)|	66 (52 to 78)	81 (71 to 89)		
Ser Y - hSBA ≥1:4, at 12 months of age(n=71,86)|	85 (74 to 92)	87 (78 to 93)		
Ser Y - hSBA ≥1:8, at 12 months of age(n=71,86)|	70 (58 to 81)	79 (69 to 87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMTs) following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point title	Geometric Mean hSBA Titers (GMTs) following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point description:

The persistence of immune response as measured by hSBA GMTs and associated 95% CI against N. Meningitidis serogroups A, C, W, and Y,at 12 months by groups.

End point type	Secondary

End point timeframe:

at 12 months of age

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	71	86		
Units: Titers				
geometric mean (confidence interval				

95%)				
Ser A - at 12 months of age (n=58,79)|	3.02 (2.55 to 3.57)	3.93 (3.4 to 4.54)		
Ser C - at 12 months of age (n=70,84)|	7.56 (5.61 to 10)	14 (10 to 18)		
Ser W - at 12 months of age (n=58,75)|	15 (10 to 21)	20 (15 to 27)		
Ser Y - at 12 months of age (n=71,86)|	18 (13 to 24)	22 (17 to 29)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point description:

The induction of immunological memory was measured as percentages of subjects with hSBA ≥ 1:4 and hSBA ≥ 1:8 and associated 95% CI, against N. Meningitidis serogroups A, C, W, and Y , before challenge at 12 months of age and 1 month after PS challenge.

End point type	Secondary

End point timeframe:

before challenge at 12 months of age and 1 month after PS challenge.

End point values	CA246+ (MenACWY Ad+ at 2,4,6 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	44			
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4,before challenge at 12m (n=44)|	27 (15 to 43)			
Ser A - hSBA ≥1:4, 1 month after PS (n=44)|	89 (75 to 96)			
Ser A-hSBA ≥1:8,before challenge at 12m (n=44)|	23 (11 to 38)			
Ser A - hSBA ≥1:8, 1 month after PS (n=44)|	86 (73 to 95)			
Ser C-hSBA ≥1:4,before challenge at 12m (n=43)|	74 (59 to 86)			
Ser C - hSBA ≥1:4, 1 month after PS (n=43)|	95 (84 to 99)			
Ser C-hSBA ≥1:8, before challenge at 12m (n=43)|	65 (49 to 79)			
Ser C - hSBA ≥1:8, 1 month after PS (n=43)|	91 (78 to 97)			
Ser W-hSBA ≥1:4,before challenge at 12m (n=40)|	83 (67 to 93)			

Ser W - hSBA ≥1:4, 1 month after PS (n=40)|	98 (87 to 100)			
Ser W-hSBA ≥1:8,before challenge at 12m (n=40)|	73 (56 to 85)			
Ser W - hSBA ≥1:8, 1 month after PS (n=40)|	95 (83 to 99)			
Ser Y-hSBA ≥1:4,before challenge at 12m (n=44)|	89 (75 to 96)			
Ser Y - hSBA ≥1:4, 1 month after PS (n=44)|	98 (88 to 100)			
Ser Y-hSBA ≥1:8,before challenge at 12m (N=44)|	77 (62 to 89)			
Ser Y - hSBA ≥1:8, 1 month after PS (n=44)|	98 (88 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMTs) in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point title	Geometric Mean hSBA Titers (GMTs) in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following 3 doses of Novartis MenACWY Ad+ conjugate vaccine

End point description:

The induction of immunological memory was measured as hSBA Geometric Mean Titers (GMTs) and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y , before challenge at 12 months of age and 1 month after PS challenge.

End point type	Secondary

End point timeframe:

before challenge at 12 months of age and 1 month after PS challenge.

End point values	CA246+ (MenACWY Ad+ at 2, 4,6 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	44			
Units: titers				
geometric mean (confidence interval 95%)				
Ser A-before challenge at 12m of age(n=44)	3.4 (2.75 to 4.2)			
Ser A-1 m after PS challenge (n=44)	32 (21 to 48)			
Ser C-before challenge at 12m of age(n=43)	12 (8.41 to 18)			
Ser C-1m after PS challenge (n=43)	82 (50 to 133)			
Ser W-before challenge at 12m of age(n=40)	17 (11 to 25)			
Ser W-1m after PS challenge (n=40)	249 (152 to 410)			

Ser Y-before challenge at 12m of age(n=44)	19 (13 to 28)			
Ser Y-1m after PS challenge (n=44)	186 (117 to 294)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following two doses of Novartis MenACWY Ad+ or MenACWY Ad- conjugate vaccine

End point title	Percentages of Subjects With hSBA Titers ≥ 1:4 or ≥ 1:8 in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following two doses of Novartis MenACWY Ad+ or MenACWY Ad- conjugate vaccine

End point description:

The Induction of immunological memory was measured as percentage of subjects with hSBA ≥ 1:4, hSBA ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y, before challenge at 12 months and 1 month after PS challenge by groups.

End point type	Secondary

End point timeframe:

Before challenge at 12 months of age and 1 month after PS challenge.

End point values	CA24+ (MenACWY Ad+ at 2, 4m)	CA24- (MenACWY Ad- at 2, 4m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	39		
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4,before challenge @ 12m (n=40,39)	8 (2 to 20)	8 (2 to 21)		
Ser A-hSBA≥1:4,1m after PS (n=40,39)|	78 (62 to 89)	92 (79 to 98)		
Ser A-hSBA≥1:8,before challenge at 12m (n=40,39)|	5 (1 to 17)	5 (1 to 17)		
Ser A-hSBA ≥1:8, 1m after PS (n=40,39)|	78 (62 to 89)	87 (73 to 96)		
Ser C-hSBA≥1:4,before challenge at 12m (n=41,39)|	44 (28 to 60)	38 (23 to 55)		
Ser C hSBA ≥1:4, 1m after PS (n=41,39)|	95 (83 to 99)	95 (83 to 99)		
Ser C-hSBA≥1:8,before challenge at 12m(n=41,39)|	39 (24 to 55)	36 (21 to 53)		
Ser C-hSBA ≥1:8, 1m after PS (n=41,39)	93 (80 to 98)	90 (76 to 97)		
Ser W-hSBA≥1:4,before challenge at 12m(n=41,38)	59 (42 to 74)	71 (54 to 85)		
Ser W-hSBA≥1:4, 1m after PS (n=41,38)	98 (87 to 100)	100 (91 to 100)		
Ser W-hSBA≥1:8,before challenge at 12m(n=41,38)	51 (35 to 67)	58 (41 to 74)		

Ser W-hSBA≥1:8, 1m after PS (n=41,38)	98 (87 to 100)	100 (91 to 100)		
Ser Y-hSBA ≥1:4,before challenge at 12m(n=42,38)	55 (39 to 70)	55 (38 to 71)		
Ser Y-hSBA ≥1:4, 1m after PS (n=42,38)	98 (87 to 100)	100 (91 to 100)		
Ser Y-hSBA≥1:8,before challenge at 12m (n=42,38)	50 (34 to 66)	42 (26 to 59)		
Ser Y-hSBA≥1:8, 1m after PS (n=42,38)	98 (87 to 100)	97 (86 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean hSBA Titers (GMTs) in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following two doses of Novartis MenACWY Ad+ or MenACWY Ad- conjugate vaccine

End point title	Geometric Mean hSBA Titers (GMTs) in subjects challenged with a reduced dose of licensed Meningococcal ACWY PS vaccine following two doses of Novartis MenACWY Ad+ or MenACWY Ad- conjugate vaccine

End point description:

Induction of immunological memory was measured by hSBA Geometric Mean Titers (GMTs) and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y, before challenge at 12 months and 1 month after PS challenge by groups.

End point type	Secondary

End point timeframe:

Before challenge at 12 months of age and 1 month after PS challenge.

End point values	CA24+ (MenACWY Ad+ at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	39		
Units: titers				
geometric mean (confidence interval 95%)				
Ser A - before challenge at 12 months (n=40,39)|	2.22 (1.77 to 2.76)	2.31 (1.84 to 2.89)		
Ser A - 1 month after PS challenge (n=40,39)|	28 (18 to 44)	55 (35 to 86)		
Ser C - before challenge at 12 months (n=41,39)|	5.21 (3.51 to 7.72)	5.07 (3.38 to 7.59)		
Ser C - 1 month after PS challenge (n=41,39)|	140 (85 to 231)	181 (109 to 301)		
Ser W - before challenge at 12 months (n=41,38)|	7.48 (4.94 to 11)	11 (7.08 to 17)		
Ser W - 1 month after PS challenge (n=41,38)|	365 (224 to 597)	555 (333 to 924)		
Ser Y - before challenge at 12 months (n=42,38)|	6.73 (4.51 to 10)	6.79 (4.45 to 10)		

Ser Y - 1 month after PS challenge (n=42,38)|	280 (175 to 448)	288 (176 to 472)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 of MenACWY Ad+ conjugate vaccine

End point title	Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 of MenACWY Ad+ conjugate vaccine

End point description:

The immunogenicity was measured as percentages of subject with hSBA≥ 1:4 and hSBA ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y, baseline and 1 month after 2 or 3 dose primary series by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after the 2 or 3 dose primary vaccination series

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6m)	UK24+ (MenACWY Ad+ at 2, 4 m)	CA24+ (MenACWY Ad+ at 2, 4m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	81	87	77	79
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A-hSBA≥1:4, baseline (n=69,80,38,79)	6 (2 to 14)	0 (0 to 5)	4 (1 to 12)	3 (0 to 9)
Ser A-hSBA≥1:4,1m after 1st vac(n=69,80,38,79)	93 (84 to 98)	81 (71 to 89)	60 (48 to 72)	66 (54 to 76)
Ser A-hSBA≥1:8, baseline (n=69,80,38,79)	4 (1 to 12)	0 (0 to 5)	3 (0 to 10)	1 (0.032 to 7)
Ser A-hSBA≥1:8,1m after 1st vac (n=69,80,38,79)	88 (78 to 95)	76 (65 to 85)	54 (42 to 67)	58 (47 to 69)
Ser C -hSBA≥1:4, baseline (n=79,86,40,74)	18 (10 to 28)	15 (8 to 24)	13 (6 to 23)	15 (8 to 25)
Ser C-hSBA≥1:4,1m after 1st vac(n=79,86,40,74)	96 (89 to 99)	98 (92 to 100)	84 (74 to 92)	91 (81 to 96)
Ser C-hSBA≥1:8, baseline (n=79,86,40,74)	9 (4 to 17)	5 (1 to 11)	9 (4 to 18)	15 (8 to 25)
Ser C-hSBA≥1:8,1m after 1st vac(n=79,86,40,74)	92 (84 to 97)	98 (92 to 100)	83 (73 to 91)	85 (75 to 92)
Ser W - hSBA ≥1:4, baseline (n=69,78,73,74)|	54 (41 to 66)	31 (21 to 42)	45 (34 to 57)	24 (15 to 36)
Ser W-hSBA≥1:4,1m after 1st vac(n=69,78,73,74)	97 (90 to 100)	99 (93 to 100)	92 (83 to 97)	91 (81 to 96)
Ser W-hSBA≥1:8, baseline (n=69,78,73,74)	46 (34 to 59)	28 (19 to 40)	37 (26 to 49)	19 (11 to 30)
Ser W-hSBA≥1:8,1m after 1st vac(n=69,78,73,74)	88 (78 to 95)	96 (89 to 99)	84 (73 to 91)	85 (75 to 92)

Ser Y-hSBA≥1:4, baseline (n=81,87,76,74)	21 (13 to 31)	17 (10 to 27)	18 (10 to 29)	9 (4 to 19)
Ser Y-hSBA≥1:4,1m after 1st vac(n=81,87,76,74)	94 (86 to 98)	98 (92 to 100)	84 (74 to 92)	86 (77 to 93)
Ser Y-hSBA ≥1:8, baseline (n=81,87,76,74)	14 (7 to 23)	11 (6 to 20)	7 (2 to 15)	4 (1 to 11)
Ser Y-hSBA≥1:8,1m after 1st vac(n=81,87,76,74)	93 (85 to 97)	89 (80 to 94)	76 (65 to 85)	80 (69 to 88)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 in subjects challenged with a reduced dose of a licensed Meningococcal ACWY PS vaccine following 2 or 3 doses of MenACWY Ad+ conjugate vaccine

End point title	Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 in subjects challenged with a reduced dose of a licensed Meningococcal ACWY PS vaccine following 2 or 3 doses of MenACWY Ad+ conjugate vaccine

End point description:

The memory response was measured as percentages of subjects with hSBA ≥ 1:4 and hSBA ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroups A, C, W, and Y, at 12 months of age and 1 month after PS challenge by groups.

End point type	Secondary

End point timeframe:

at 12 months of age and 1 month after PS challenge

End point values	CA24+ (MenACWY Ad+ at 2, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	44		
Units: percentages of subjects				
number (confidence interval 95%)				
Ser A - hSBA ≥1:4, at 12 months of age (n=44,40)|	8 (2 to 20)	27 (15 to 43)		
Ser A - hSBA ≥1:4, at 1 month after PS (n=44,40)|	78 (62 to 89)	89 (75 to 96)		
Ser A - hSBA ≥1:8, at 12 months of age (n=44,40)|	5 (1 to 17)	23 (11 to 38)		
Ser A - hSBA ≥1:8, at 1 month after PS (n=44,40)|	78 (62 to 89)	86 (73 to 95)		
Ser C - hSBA ≥1:4, at 12 months of age (n=43,41)|	44 (28 to 60)	74 (59 to 86)		
Ser C - hSBA ≥1:4, at 1 month after PS (n=43,41)|	95 (83 to 99)	95 (84 to 99)		
Ser C - hSBA ≥1:8, at 12 months of age (n=43,41)|	39 (24 to 55)	65 (49 to 79)		
Ser C - hSBA ≥1:8, at 1 month after PS (n=43,41)|	93 (80 to 98)	91 (78 to 97)		

Ser W - hSBA ≥1:4, at 12 months of age (n=40,41)|	59 (42 to 74)	83 (67 to 93)		
Ser W - hSBA ≥1:4, at 1 month after PS (n=40,41)|	98 (87 to 100)	98 (87 to 100)		
Ser W - hSBA ≥1:8, at 12 months of age (n=40,41)|	51 (35 to 67)	73 (56 to 85)		
Ser W - hSBA ≥1:8, at 1 month after PS (n=40,41)|	98 (87 to 100)	95 (83 to 99)		
Ser Y - hSBA ≥1:4, at 12 months of age (n=44,42)|	55 (39 to 70)	89 (75 to 96)		
Ser Y - hSBA ≥1:4, at 1 month after PS (n=44,42)|	98 (87 to 100)	98 (88 to 100)		
Ser Y - hSBA ≥1:8, at 12 months of age (n=44,42)|	50 (34 to 66)	77 (62 to 89)		
Ser Y - hSBA ≥1:8, at 1 month after PS (n=44,42)|	98 (87 to 100)	98 (88 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with Antibody response to routine vaccines (Hib, Diphtheria, Tetanus, Hepatitis B) when routine vaccines are given concomitantly with Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines

End point title	Percentages of subjects with Antibody response to routine vaccines (Hib, Diphtheria, Tetanus, Hepatitis B) when routine vaccines are given concomitantly with Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines

End point description:

To assess the immunogenicity of routine vaccines when given concomitantly to Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines. Hib, diphtheria, tetanus, pertussis will be evaluated as the first priority, followed by pneumococcus, polio, hepatitis B, and MMR (measles, mumps, and rubella) depending on the availability of sera.

End point type	Secondary

End point timeframe:

Baseline and 1 month after the 2 or 3 dose primary vaccination series

End point values	CA24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)	UK234+ (MenACWY Ad+ at 2, 3, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	70	77	70	73
Units: percentages of subjects				
number (confidence interval 95%)				
Antitetanus≥0.1 IU/mL-baseline(69,71,70,67,69,72)	75 (64 to 85)	79 (68 to 88)	70 (58 to 80)	93 (83 to 98)
Antitetanus≥0.1 IU/mL-1m post (69,71,70,67,69,72)	100 (95 to 100)	100 (95 to 100)	99 (92 to 100)	100 (95 to 100)
antidipht≥0.1 IU/mL-baseline(69,71,70,67,69,72)	17 (9 to 28)	14 (7 to 24)	3 (0 to 10)	18 (10 to 29)

antidipht≥0.1 IU/mL- 1m post (69,71,70,67,69,72)	96 (88 to 99)	97 (90 to 100)	100 (95 to 100)	97 (90 to 100)
antiPRPtiter≥0.15µg/mL-baseline(70,77,69,73,72,73)	36 (25 to 48)	42 (30 to 53)	17 (9 to 28)	25 (15 to 36)
antiPRPtiter≥0.15µg/mL-1m post (70,77,69,73,72,73)	74 (62 to 84)	95 (87 to 99)	67 (54 to 78)	97 (90 to 100)
antiPRPtiter≥1.0 µg/mL-baseline(70,77,69,73,72,73)	10 (4 to 20)	17 (9 to 27)	3 (0 to 10)	7 (2 to 15)
antiPRPtiter≥1.0 µg/mL-1m post (70,77,69,73,72,73)	33 (22 to 45)	86 (76 to 93)	35 (24 to 47)	82 (71 to 90)
antiHBVtiter≥1.0 IU/mL-baseline(65,na,66,na,na,67)	23 (14 to 35)	999 (999 to 999)	11 (4 to 21)	999 (999 to 999)
antiHBVtiter≥1.0 IU/mL-1m post (65,na,66,na,na,67)	85 (74 to 92)	999 (999 to 999)	92 (83 to 97)	999 (999 to 999)

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	72	73		
Units: percentages of subjects				
number (confidence interval 95%)				
Antitetanus≥0.1 IU/mL-baseline(69,71,70,67,69,72)	87 (77 to 94)	71 (59 to 81)		
Antitetanus≥0.1 IU/mL-1m post (69,71,70,67,69,72)	100 (95 to 100)	100 (95 to 100)		
antidipht≥0.1 IU/mL-baseline(69,71,70,67,69,72)	19 (10 to 30)	15 (8 to 26)		
antidipht≥0.1 IU/mL- 1m post (69,71,70,67,69,72)	96 (88 to 99)	100 (95 to 100)		
antiPRPtiter≥0.15µg/mL-baseline(70,77,69,73,72,73)	49 (37 to 61)	37 (26 to 49)		
antiPRPtiter≥0.15µg/mL-1m post (70,77,69,73,72,73)	97 (90 to 100)	100 (95 to 100)		
antiPRPtiter≥1.0 µg/mL-baseline(70,77,69,73,72,73)	17 (9 to 27)	11 (5 to 20)		
antiPRPtiter≥1.0 µg/mL-1m post (70,77,69,73,72,73)	82 (71 to 90)	86 (76 to 93)		
antiHBVtiter≥1.0 IU/mL-baseline(65,na,66,na,na,67)	999 (999 to 999)	22 (13 to 34)		
antiHBVtiter≥1.0 IU/mL-1m post (65,na,66,na,na,67)	999 (999 to 999)	97 (90 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: ELISA GMT Concentrations for routine vaccines (Hib, diphtheria, tetanus, Hepatitis B) when given concomitantly with Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate vaccines for Hib, Diphtheria, Tetanus, Hepatitis B

End point title	ELISA GMT Concentrations for routine vaccines (Hib, diphtheria, tetanus, Hepatitis B) when given concomitantly with Novartis MenACWY Ad+ or Novartis MenACWY Ad- conjugate

	vaccines for Hib, Diphtheria, Tetanus, Hepatitis B

End point description:

To assess the Enzyme-linked immunosorbent assay (ELISA) GMT of Hib, Diphtheria, Tetanus, Hepatitis B, administered Concomitantly with Novartis MenACWY Ad+ or MenACWY Ad-conjugate vaccines, at the baseline and 1 month after primary vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after the 2 or 3 dose primary vaccination series

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)	CA24+ (MenACWY Ad+ at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	77	70	70	73
Units: titers				
geometric mean (confidence interval 95%)				
Tetanus - baseline (n=69,71,70,67,69,72)	0.31 (0.24 to 0.4)	0.32 (0.24 to 0.41)	0.23 (0.18 to 0.29)	0.28 (0.22 to 0.37)
Tetanus - 1 m after 1st vac(n=69,71,70,67,69,72)	0.92 (0.75 to 1.13)	0.7 (0.57 to 0.87)	1.4 (1.14 to 1.72)	0.6 (0.48 to 0.73)
Diphtheria - baseline (n=69,71,70,67,69,72)	0.04 (0.03 to 0.053)	0.035 (0.026 to 0.047)	0.027 (0.02 to 0.035)	0.031 (0.024 to 0.042)
Diphtheria -1m after 1st vac(n=69,71,70,67,69,72)	1.02 (0.82 to 1.28)	1.02 (0.81 to 1.29)	1.72 (1.38 to 2.14)	1.06 (0.84 to 1.32)
Hib - baseline (n=70,77,69,73,72,73)	0.15 (0.11 to 0.21)	0.078 (0.056 to 0.11)	0.11 (0.078 to 0.15)	0.089 (0.063 to 0.12)
Hib - 1 m after 1st vac(n=70,77,69,73,72,73)	4.55 (3.08 to 6.72)	4.63 (3.14 to 6.83)	4.53 (3.07 to 6.68)	0.47 (0.32 to 0.7)
Hepatitis B - baseline (n=65,na,66,na,na,67)	999 (999 to 999)	999 (999 to 999)	5.9 (4.25 to 8.2)	5.79 (4.15 to 8.09)
Hepatitis B-1m after 1st vac(n=65,na,66,na,na,67)	999 (999 to 999)	999 (999 to 999)	378 (258 to 554)	69 (47 to 102)

End point values	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	72	73		
Units: titers				
geometric mean (confidence interval 95%)				
Tetanus - baseline (n=69,71,70,67,69,72)	0.25 (0.19 to 0.32)	0.18 (0.14 to 0.23)		
Tetanus - 1 m after 1st vac(n=69,71,70,67,69,72)	0.97 (0.79 to 1.19)	0.68 (0.55 to 0.83)		
Diphtheria - baseline (n=69,71,70,67,69,72)	0.032 (0.024 to 0.042)	0.016 (0.012 to 0.021)		
Diphtheria -1m after 1st vac(n=69,71,70,67,69,72)	0.98 (0.78 to 1.22)	1.49 (1.19 to 1.87)		
Hib - baseline (n=70,77,69,73,72,73)	0.15 (0.11 to 0.21)	0.064 (0.045 to 0.09)		

Hib - 1 m after 1st vac(n=70,77,69,73,72,73)	5.67 (3.89 to 8.28)	0.42 (0.28 to 0.63)		
Hepatitis B - baseline (n=65,na,66,na,na,67)	999 (999 to 999)	4.21 (3.03 to 5.87)		
Hepatitis B-1m after 1st vac(n=65,na,66,na,na,67)	999 (999 to 999)	133 (90 to 195)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 against N. Meningitidis Serogroup C following 2 doses of MenACWY Ad+ or Ad- conjugate vaccine (containing 5 µg of MenC oligosaccharide) or 2 doses of Menjugate (containing 10 µg of MenC oligosaccharide)

End point title	Percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 against N. Meningitidis Serogroup C following 2 doses of MenACWY Ad+ or Ad- conjugate vaccine (containing 5 µg of MenC oligosaccharide) or 2 doses of Menjugate (containing 10 µg of MenC oligosaccharide)

End point description:

The immunogenicity was measured as percentages of subjects with hSBA ≥ 1:4 and ≥ 1:8 and associated 95% CI, directed against N. Meningitidis serogroup C, at baseline and 1 month after second vaccination by groups.

End point type	Secondary

End point timeframe:

Baseline and 1 month after second vaccination

End point values	UK24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)	UKMenC (Menjugate at 2, 4 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	77	79	85	40
Units: percentages of subjects				
number (confidence interval 95%)				
hSBA ≥1:4, baseline	13 (6 to 23)	20 (12 to 31)	20 (12 to 30)	23 (11 to 38)
hSBA ≥1:4, 1 month after second vaccination	84 (74 to 92)	86 (76 to 93)	93 (85 to 97)	98 (87 to 100)
hSBA ≥1:8, baseline	9 (4 to 18)	5 (1 to 12)	11 (5 to 19)	10 (3 to 24)
hSBA ≥1:8, 1 month after second vaccination	83 (73 to 91)	82 (72 to 90)	89 (81 to 95)	98 (87 to 100)

End point values	CA24+ (MenACWY Ad+ at 2, 4 m)			
Subject group type	Subject analysis set			
Number of subjects analysed	74			
Units: percentages of subjects				
number (confidence interval 95%)				

hSBA ≥1:4, baseline	15 (8 to 25)			
hSBA ≥1:4, 1 month after second vaccination	91 (81 to 96)			
hSBA ≥1:8, baseline	15 (8 to 25)			
hSBA ≥1:8, 1 month after second vaccination	85 (75 to 92)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Solicited Local and Systemic Adverse Events After 2 or 3 Dose Primary Vaccination series with MenACWY Ad+ or MenACWY Ad-

End point title	Number of Subjects Reporting Solicited Local and Systemic Adverse Events After 2 or 3 Dose Primary Vaccination series with MenACWY Ad+ or MenACWY Ad-

End point description:

Safety and tolerability of Novartis MenACWY Ad+ and MenACWY Ad- conjugate vaccine when given in a 2 or 3 dose primary vaccination series concomitantly with licensed pediatric vaccines.

End point type	Secondary

End point timeframe:

7 days after each vaccination

End point values	UK234+ (MenACWY Ad+ at 2, 3, 4 m)	UK24+ (MenACWY Ad+ at 2, 4 m)	UKMenC (Menjugate at 2, 4 m)	CA246+ (MenACWY Ad+ at 2, 4, 6 m)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	90	90	45	98
Units: subjects				
Tenderness	40	31	18	46
Erythema	69	64	34	73
Induration	21	24	12	36
Eating habit Change	28	25	9	35
Sleepiness	56	49	25	64
Persistent Crying	7	7	6	15
Irritability	63	71	31	80
Vomiting	19	26	9	23
Diarrhea	29	27	12	30
Fever (≥38°C)	7	4	1	14
Analgesics/Antipyretics	43	35	18	61

End point values	CA24+ (MenACWY Ad+ at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)	CA24- (MenACWY Ad- at 2, 4 m)	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	98	90	90	
Units: subjects				
Tenderness	32	41	35	
Erythema	67	78	66	
Induration	18	40	24	
Eating habit Change	27	21	20	
Sleepiness	62	45	52	
Persistent Crying	4	5	4	
Irritability	70	61	73	
Vomiting	15	14	11	
Diarrhea	22	18	16	
Fever (≥38°C)	7	5	5	
Analgesics/Antipyretics	46	36	45	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting Solicited Local and Systemic Adverse Events After MenACWY Ad+ and MenACWY Ad- Booster or Polysaccharide Challenge Administered at 12 months of age

End point title	Number of Subjects Reporting Solicited Local and Systemic Adverse Events After MenACWY Ad+ and MenACWY Ad- Booster or Polysaccharide Challenge Administered at 12 months of age[2]

End point description:

The safety profile of Novartis MenACWY Ad+ and MenACWY Ad- conjugate vaccines when given at 12 months of age.

End point type	Secondary

End point timeframe:

7 days after vaccination at 12 months of age

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: descriptive statistics.

End point values	UK234+ (MenACWY Ad+ at 2,3,4 m)	UK24+ (MenACWY Ad+ at 2, 4 m)	UKMenC (Menjugate at 2, 4 m)	UK24- (MenACWY Ad- at 2, 4 m)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	90	90	45	90
Units: subjects				
Tenderness	7	11	10	10
Erythema	62	58	36	66
Induration	21	32	18	36
Eating habit change	11	16	5	13
Sleepiness	11	14	9	16
Persistent crying	0	4	3	4
Irritability	26	32	20	28
Vomiting	4	6	4	8

Diarrhea	9	9	4	9
Fever (≥38°C)	3	7	2	14
Analgesics/Antipyretics	14	21	12	22

End point values	CA246+ (MenACWY Ad+ at 2, 4, 6 m) - No Treatment	CA246+ (MenACWY Ad+ at 2, 4, 6 m) - PS	CA24+ (MenACWY Ad+ at 2, 4 m) - ACWY	CA24+ (MenACWY Ad+ at 2, 4 m) - PS
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	48	48	47	48
Units: subjects				
Tenderness	0	10	7	10
Erythema	0	21	27	30
Induration	0	12	9	9
Eating habit change	10	12	6	10
Sleepiness	10	8	7	13
Persistent crying	3	3	0	2
Irritability	24	23	19	24
Vomiting	2	7	0	4
Diarrhea	4	7	6	5
Fever (≥38°C)	3	6	1	8
Analgesics/Antipyretics	13	15	8	17

End point values	CA24- (MenACWY Ad- at 2, 4 m) - ACWY	CA24- (MenACWY Ad- at 2, 4 m) - PS		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	44	43		
Units: subjects				
Tenderness	7	12		
Erythema	21	26		
Induration	10	15		
Eating habit change	10	8		
Sleepiness	9	7		
Persistent crying	5	0		
Irritability	17	20		
Vomiting	5	4		
Diarrhea	3	4		
Fever (≥38°C)	4	1		
Analgesics/Antipyretics	14	11		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All solicited adverse events (AEs) were collected upto Day 7 after each vaccination. All SAEs and unsolicited AEs were collected throughout the study (22 months in total).

Adverse event reporting additional description:

Information on all AEs was to be collected for 7 days following each vaccination, after which information on only SAEs and AEs necessitating a physician's visit and/or resulting in premature withdrawal of subjects from the study was collected until the next study visit and recorded by study personnel.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	9.1

Reporting groups

Reporting group title	UK234+ (MenACWY Ad+ at 2,3,4 m)

Reporting group description:

Three doses of MenACWY Ad+ vaccine were to be given at 1-month intervals concomitantly with DTaPHibIPV at 2, 3, and 4 months of age. A fourth dose of MenACWY Ad+ was to be given at 12 months of age.

Reporting group title	UK24+ (MenACWY Ad+ at 2,4 m)

Reporting group description:

Two doses of MenACWY Ad+ vaccine were to be given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad+ vaccine was to be given at 12 months of age.

Reporting group title	UKMenC (Menjugate at 2,4m)

Reporting group description:

Two doses of Menjugate® were to be given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. One dose of MenACWY Ad+ vaccine was to be given at 12 months of age.

Reporting group title	CA246+ (MenACWY Ad+ at 2,4,6m)

Reporting group description:

Three doses of MenACWY Ad+ vaccine were to be given at 2-month intervals concomitantly with DTaPHibIPV, HBV, and Prevnar® at 2, 4, and 6 months of age (Prevnar at 6 months was optional and was given if available). One subgroup of subjects was to be given a reduced dose of MenACWY PS vaccine concomitantly with MMR (and Prevnar, if available) at 12 months of age. Another subgroup was to be administered one dose of MMR (and Prevnar, if available) at 12 months of age.

Reporting group title	CA24+ (MenACWY Ad+ at 2,4m)

Reporting group description:

Two doses of MenACWY Ad+ vaccine were to be given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar at 2 and 4 months of age.One dose of MenACWY Ad+ vaccine or one reduced dose (one fifth) of MenACWY PS vaccine was to be given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Reporting group title	UK24- (MenACWY Ad- at 2,4m)

Reporting group description:

Two doses of MenACWY Ad- vaccine were to be given at a 2-month interval concomitantly with DTaPHibIPV at 2 and 4 months of age. A third dose of MenACWY Ad- vaccine was to be given at 12 months of age.

Reporting group title	CA24- (MenACWY Ad- at 2,4m)

Reporting group description:

Two doses of MenACWY Ad- vaccine were to be given at a 2-month interval concomitantly with DTaPHibIPV, HBV, and Prevnar® at 2 and 4 months of age.One dose of MenACWY Ad- vaccine or one reduced dose (one fifth) of MenACWY PS vaccine was to be given concomitantly with MMR (and Prevnar, if available) at 12 months of age.

Serious adverse events	UK234+ (MenACWY Ad+ at 2,3,4 m)	UK24+ (MenACWY Ad+ at 2,4 m)	UKMenC (Menjugate at 2,4m)
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 90 (22.22%)	17 / 90 (18.89%)	6 / 45 (13.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Surgical and medical procedures			
ACROCHORDON EXCISION			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
CIRCUMCISION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
HYDROCELE OPERATION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
INGUINAL HERNIA REPAIR			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
TENDON SHEATH INCISION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
VOMITING			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
CYST			

subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
DEVELOPMENTAL DELAY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
BRONCHIAL HYPERREACTIVITY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
WHEEZING			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
BURNS SECOND DEGREE			

subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
FEMUR FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
HEAD INJURY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
INJURY			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
LIMB CRUSHING INJURY			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
CONGENITAL MEGACOLON			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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
HYPOSPADIAS			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
PLAGIOCEPHALY			

subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
Cardiac disorders			
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CONVULSION			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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 CONVULSION			
subjects affected / exposed	1 / 90 (1.11%)	1 / 90 (1.11%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
IDIOPATHIC THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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
INGUINAL HERNIA			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
Skin and subcutaneous tissue disorders			
ERYTHEMA MULTIFORME			

subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
PETECHIAE			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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
RASH			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
URINARY RETENTION			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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			
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
BRONCHIOLITIS			
subjects affected / exposed	4 / 90 (4.44%)	3 / 90 (3.33%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROUP INFECTIOUS			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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
GASTROENTERITIS			
subjects affected / exposed	0 / 90 (0.00%)	2 / 90 (2.22%)	0 / 45 (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
GASTROENTERITIS VIRAL			

subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (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
INFECTED CYST			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 90 (1.11%)	1 / 90 (1.11%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 90 (0.00%)	2 / 90 (2.22%)	0 / 45 (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 SYNCYTIAL VIRUS BRONCHIOLITIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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 SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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 TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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

SALMONELLOSIS			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (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 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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
VIRAL INFECTION			
subjects affected / exposed	4 / 90 (4.44%)	2 / 90 (2.22%)	1 / 45 (2.22%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIRAL RASH			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (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

Serious adverse events	CA246+ (MenACWY Ad+ at 2,4,6m)	CA24+ (MenACWY Ad+ at 2,4m)	UK24- (MenACWY Ad- at 2,4m)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 98 (9.18%)	4 / 98 (4.08%)	10 / 90 (11.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Surgical and medical procedures			
ACROCHORDON EXCISION			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
CIRCUMCISION			

subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
HYDROCELE OPERATION			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
INGUINAL HERNIA REPAIR			
subjects affected / exposed	2 / 98 (2.04%)	0 / 98 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TENDON SHEATH INCISION			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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			
VOMITING			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
CYST			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
DEVELOPMENTAL DELAY			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	2 / 90 (2.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
FOOD ALLERGY			

subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
BRONCHIAL HYPERREACTIVITY			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 90 (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
WHEEZING			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
Injury, poisoning and procedural complications			
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BURNS SECOND DEGREE			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
FEMUR FRACTURE			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
HEAD INJURY			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

INJURY			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
LIMB CRUSHING INJURY			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
TRAUMATIC FRACTURE			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
Congenital, familial and genetic disorders			
CONGENITAL MEGACOLON			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
HYPOSPADIAS			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
PLAGIOCEPHALY			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
Cardiac disorders			
SUPRAVENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
Nervous system disorders			
CONVULSION			

subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 CONVULSION			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 90 (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
Blood and lymphatic system disorders			
IDIOPATHIC THROMBOCYTOPENIC PURPURA			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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			
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
INGUINAL HERNIA			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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			
ERYTHEMA MULTIFORME			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PETECHIAE			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
RASH			

subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
Renal and urinary disorders			
URINARY RETENTION			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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			
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BRONCHIOLITIS			
subjects affected / exposed	2 / 98 (2.04%)	1 / 98 (1.02%)	2 / 90 (2.22%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROUP INFECTIOUS			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 90 (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
GASTROENTERITIS			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 VIRAL			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTED CYST			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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 SYNCYTIAL VIRUS BRONCHIOLITIS			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	0 / 90 (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
RESPIRATORY SYNCYTIAL VIRUS INFECTION			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
SALMONELLOSIS			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	1 / 90 (1.11%)
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 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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
VIRAL INFECTION			
subjects affected / exposed	1 / 98 (1.02%)	0 / 98 (0.00%)	0 / 90 (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
VIRAL RASH			
subjects affected / exposed	0 / 98 (0.00%)	0 / 98 (0.00%)	0 / 90 (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	CA24- (MenACWY Ad- at 2,4m)		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 90 (7.78%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Surgical and medical procedures			
ACROCHORDON EXCISION			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CIRCUMCISION			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYDROCELE OPERATION			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
INGUINAL HERNIA REPAIR			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

TENDON SHEATH INCISION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
VOMITING				
alternative assessment type: Systematic				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
CYST				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
DEVELOPMENTAL DELAY				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
FOOD ALLERGY				
subjects affected / exposed	0 / 90 (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	2 / 90 (2.22%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
BRONCHIAL HYPERREACTIVITY				
subjects affected / exposed	1 / 90 (1.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
WHEEZING				

subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BURNS SECOND DEGREE			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
FEMUR FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HEAD INJURY			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
INJURY			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
LIMB CRUSHING INJURY			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
TRAUMATIC FRACTURE			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			

CONGENITAL MEGACOLON				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HYPOSPADIAS				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PLAGIOCEPHALY				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
SUPRAVENTRICULAR TACHYCARDIA				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
CONVULSION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FEBRILE CONVULSION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
IDIOPATHIC THROMBOCYTOPENIC PURPURA				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
GASTROOESOPHAGEAL REFLUX DISEASE				

subjects affected / exposed	1 / 90 (1.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
INGUINAL HERNIA			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
ERYTHEMA MULTIFORME			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PETECHIAE			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
RASH			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
URINARY RETENTION			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
ARTHRITIS BACTERIAL			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BRONCHIOLITIS			
subjects affected / exposed	2 / 90 (2.22%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

CROUP INFECTIOUS				
subjects affected / exposed	1 / 90 (1.11%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
GASTROENTERITIS				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
GASTROENTERITIS VIRAL				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
INFECTED CYST				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
INFLUENZA				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
LOWER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY SYNCYTIAL VIRUS BRONCHIOLITIS				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY SYNCYTIAL VIRUS				

INFECTION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
RESPIRATORY TRACT INFECTION VIRAL				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SALMONELLOSIS				
subjects affected / exposed	0 / 90 (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 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VARICELLA				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VIRAL INFECTION				
subjects affected / exposed	0 / 90 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VIRAL RASH				
subjects affected / exposed	0 / 90 (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	UK234+ (MenACWY Ad+ at 2,3,4 m)	UK24+ (MenACWY Ad+ at 2,4 m)	UKMenC (Menjugate at 2,4m)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	90 / 90 (100.00%)	89 / 90 (98.89%)	45 / 45 (100.00%)
Nervous system disorders			
SOMNOLENCE			
alternative assessment type: Systematic			
subjects affected / exposed	58 / 90 (64.44%)	57 / 90 (63.33%)	29 / 45 (64.44%)
occurrences (all)	58	57	29
General disorders and administration site conditions			
CRYING			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 90 (7.78%)	11 / 90 (12.22%)	8 / 45 (17.78%)
occurrences (all)	7	11	8
INJECTION SITE ERYTHEMA			
alternative assessment type: Systematic			
subjects affected / exposed	79 / 90 (87.78%)	79 / 90 (87.78%)	40 / 45 (88.89%)
occurrences (all)	79	79	40
INJECTION SITE INDURATION			
alternative assessment type: Systematic			
subjects affected / exposed	39 / 90 (43.33%)	43 / 90 (47.78%)	25 / 45 (55.56%)
occurrences (all)	39	43	25
INJECTION SITE PAIN			
alternative assessment type: Systematic			
subjects affected / exposed	42 / 90 (46.67%)	39 / 90 (43.33%)	23 / 45 (51.11%)
occurrences (all)	42	39	23
IRRITABILITY			
alternative assessment type: Systematic			
subjects affected / exposed	69 / 90 (76.67%)	82 / 90 (91.11%)	39 / 45 (86.67%)
occurrences (all)	69	82	39
PYREXIA			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 90 (12.22%)	13 / 90 (14.44%)	3 / 45 (6.67%)
occurrences (all)	11	13	3
Eye disorders			

CONJUNCTIVITIS			
subjects affected / exposed	3 / 90 (3.33%)	9 / 90 (10.00%)	3 / 45 (6.67%)
occurrences (all)	3	9	3
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	7 / 90 (7.78%)	1 / 90 (1.11%)	2 / 45 (4.44%)
occurrences (all)	7	1	2
DIARRHOEA			
alternative assessment type: Systematic			
subjects affected / exposed	41 / 90 (45.56%)	40 / 90 (44.44%)	18 / 45 (40.00%)
occurrences (all)	41	40	18
VOMITING			
alternative assessment type: Systematic			
subjects affected / exposed	24 / 90 (26.67%)	37 / 90 (41.11%)	13 / 45 (28.89%)
occurrences (all)	24	37	13
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	10 / 90 (11.11%)	7 / 90 (7.78%)	9 / 45 (20.00%)
occurrences (all)	10	7	9
NASAL CONGESTION			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
RHINORRHOEA			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
DERMATITIS DIAPER			
subjects affected / exposed	6 / 90 (6.67%)	3 / 90 (3.33%)	1 / 45 (2.22%)
occurrences (all)	6	3	1
DRY SKIN			
subjects affected / exposed	4 / 90 (4.44%)	0 / 90 (0.00%)	1 / 45 (2.22%)
occurrences (all)	4	0	1
ECZEMA			
subjects affected / exposed	8 / 90 (8.89%)	13 / 90 (14.44%)	5 / 45 (11.11%)
occurrences (all)	8	13	5
RASH			

subjects affected / exposed	3 / 90 (3.33%)	4 / 90 (4.44%)	3 / 45 (6.67%)
occurrences (all)	3	4	3
RASH PAPULAR			
subjects affected / exposed	0 / 90 (0.00%)	0 / 90 (0.00%)	0 / 45 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
EATING DISORDER			
alternative assessment type: Systematic			
subjects affected / exposed	34 / 90 (37.78%)	42 / 90 (46.67%)	17 / 45 (37.78%)
occurrences (all)	34	42	17
Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	8 / 90 (8.89%)	4 / 90 (4.44%)	1 / 45 (2.22%)
occurrences (all)	8	4	1
CROUP INFECTIOUS			
subjects affected / exposed	1 / 90 (1.11%)	0 / 90 (0.00%)	0 / 45 (0.00%)
occurrences (all)	1	0	0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	9 / 90 (10.00%)	8 / 90 (8.89%)	0 / 45 (0.00%)
occurrences (all)	9	8	0
NASOPHARYNGITIS			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 90 (0.00%)	1 / 90 (1.11%)	0 / 45 (0.00%)
occurrences (all)	0	1	0
OTITIS MEDIA			
subjects affected / exposed	6 / 90 (6.67%)	7 / 90 (7.78%)	1 / 45 (2.22%)
occurrences (all)	6	7	1
RHINITIS			
subjects affected / exposed	30 / 90 (33.33%)	34 / 90 (37.78%)	15 / 45 (33.33%)
occurrences (all)	30	34	15
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	7 / 90 (7.78%)	10 / 90 (11.11%)	8 / 45 (17.78%)
occurrences (all)	7	10	8

VIRAL INFECTION			
subjects affected / exposed	6 / 90 (6.67%)	7 / 90 (7.78%)	1 / 45 (2.22%)
occurrences (all)	6	7	1

Non-serious adverse events	CA246+ (MenACWY Ad+ at 2,4,6m)	CA24+ (MenACWY Ad+ at 2,4m)	UK24- (MenACWY Ad- at 2,4m)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	97 / 98 (98.98%)	97 / 98 (98.98%)	90 / 90 (100.00%)
Nervous system disorders			
SOMNOLENCE			
alternative assessment type: Systematic			
subjects affected / exposed	68 / 98 (69.39%)	70 / 98 (71.43%)	57 / 90 (63.33%)
occurrences (all)	68	70	57
General disorders and administration site conditions			
CRYING			
alternative assessment type: Systematic			
subjects affected / exposed	19 / 98 (19.39%)	8 / 98 (8.16%)	14 / 90 (15.56%)
occurrences (all)	19	8	14
INJECTION SITE ERYTHEMA			
alternative assessment type: Systematic			
subjects affected / exposed	73 / 98 (74.49%)	78 / 98 (79.59%)	84 / 90 (93.33%)
occurrences (all)	73	78	84
INJECTION SITE INDURATION			
alternative assessment type: Systematic			
subjects affected / exposed	42 / 98 (42.86%)	25 / 98 (25.51%)	59 / 90 (65.56%)
occurrences (all)	42	25	59
INJECTION SITE PAIN			
alternative assessment type: Systematic			
subjects affected / exposed	50 / 98 (51.02%)	41 / 98 (41.84%)	45 / 90 (50.00%)
occurrences (all)	50	41	45
IRRITABILITY			
alternative assessment type: Systematic			
subjects affected / exposed	85 / 98 (86.73%)	85 / 98 (86.73%)	77 / 90 (85.56%)
occurrences (all)	85	85	77
PYREXIA			
alternative assessment type: Systematic			

subjects affected / exposed	30 / 98 (30.61%)	22 / 98 (22.45%)	19 / 90 (21.11%)
occurrences (all)	30	22	19
Eye disorders			
CONJUNCTIVITIS			
subjects affected / exposed	3 / 98 (3.06%)	1 / 98 (1.02%)	12 / 90 (13.33%)
occurrences (all)	3	1	12
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	8 / 98 (8.16%)	6 / 98 (6.12%)	1 / 90 (1.11%)
occurrences (all)	8	6	1
DIARRHOEA			
alternative assessment type: Systematic			
subjects affected / exposed	37 / 98 (37.76%)	34 / 98 (34.69%)	36 / 90 (40.00%)
occurrences (all)	37	34	36
VOMITING			
alternative assessment type: Systematic			
subjects affected / exposed	29 / 98 (29.59%)	23 / 98 (23.47%)	28 / 90 (31.11%)
occurrences (all)	29	23	28
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 98 (3.06%)	6 / 98 (6.12%)	16 / 90 (17.78%)
occurrences (all)	3	6	16
NASAL CONGESTION			
subjects affected / exposed	3 / 98 (3.06%)	6 / 98 (6.12%)	0 / 90 (0.00%)
occurrences (all)	3	6	0
RHINORRHOEA			
subjects affected / exposed	5 / 98 (5.10%)	2 / 98 (2.04%)	0 / 90 (0.00%)
occurrences (all)	5	2	0
Skin and subcutaneous tissue disorders			
DERMATITIS DIAPER			
subjects affected / exposed	6 / 98 (6.12%)	7 / 98 (7.14%)	2 / 90 (2.22%)
occurrences (all)	6	7	2
DRY SKIN			
subjects affected / exposed	4 / 98 (4.08%)	1 / 98 (1.02%)	5 / 90 (5.56%)
occurrences (all)	4	1	5
ECZEMA			

subjects affected / exposed	15 / 98 (15.31%)	8 / 98 (8.16%)	8 / 90 (8.89%)
occurrences (all)	15	8	8
RASH			
subjects affected / exposed	5 / 98 (5.10%)	3 / 98 (3.06%)	2 / 90 (2.22%)
occurrences (all)	5	3	2
RASH PAPULAR			
subjects affected / exposed	5 / 98 (5.10%)	1 / 98 (1.02%)	0 / 90 (0.00%)
occurrences (all)	5	1	0
Psychiatric disorders			
EATING DISORDER			
alternative assessment type: Systematic			
subjects affected / exposed	45 / 98 (45.92%)	42 / 98 (42.86%)	37 / 90 (41.11%)
occurrences (all)	45	42	37
Infections and infestations			
BRONCHIOLITIS			
subjects affected / exposed	3 / 98 (3.06%)	5 / 98 (5.10%)	3 / 90 (3.33%)
occurrences (all)	3	5	3
CROUP INFECTIOUS			
subjects affected / exposed	3 / 98 (3.06%)	5 / 98 (5.10%)	1 / 90 (1.11%)
occurrences (all)	3	5	1
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 98 (2.04%)	0 / 98 (0.00%)	9 / 90 (10.00%)
occurrences (all)	2	0	9
NASOPHARYNGITIS			
subjects affected / exposed	13 / 98 (13.27%)	14 / 98 (14.29%)	0 / 90 (0.00%)
occurrences (all)	13	14	0
ORAL CANDIDIASIS			
subjects affected / exposed	2 / 98 (2.04%)	5 / 98 (5.10%)	1 / 90 (1.11%)
occurrences (all)	2	5	1
OTITIS MEDIA			
subjects affected / exposed	9 / 98 (9.18%)	7 / 98 (7.14%)	12 / 90 (13.33%)
occurrences (all)	9	7	12
RHINITIS			
subjects affected / exposed	2 / 98 (2.04%)	0 / 98 (0.00%)	39 / 90 (43.33%)
occurrences (all)	2	0	39
UPPER RESPIRATORY TRACT			

INFECTION			
subjects affected / exposed	21 / 98 (21.43%)	25 / 98 (25.51%)	3 / 90 (3.33%)
occurrences (all)	21	25	3
VIRAL INFECTION			
subjects affected / exposed	0 / 98 (0.00%)	1 / 98 (1.02%)	4 / 90 (4.44%)
occurrences (all)	0	1	4

Non-serious adverse events	CA24- (MenACWY Ad- at 2,4m)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	89 / 90 (98.89%)		
Nervous system disorders			
SOMNOLENCE			
alternative assessment type: Systematic			
subjects affected / exposed	63 / 90 (70.00%)		
occurrences (all)	63		
General disorders and administration site conditions			
CRYING			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 90 (10.00%)		
occurrences (all)	9		
INJECTION SITE ERYTHEMA			
alternative assessment type: Systematic			
subjects affected / exposed	68 / 90 (75.56%)		
occurrences (all)	68		
INJECTION SITE INDURATION			
alternative assessment type: Systematic			
subjects affected / exposed	36 / 90 (40.00%)		
occurrences (all)	36		
INJECTION SITE PAIN			
alternative assessment type: Systematic			
subjects affected / exposed	45 / 90 (50.00%)		
occurrences (all)	45		
IRRITABILITY			
alternative assessment type: Systematic			

subjects affected / exposed	82 / 90 (91.11%)		
occurrences (all)	82		
PYREXIA			
alternative assessment type: Systematic			
subjects affected / exposed	21 / 90 (23.33%)		
occurrences (all)	21		
Eye disorders			
CONJUNCTIVITIS			
subjects affected / exposed	1 / 90 (1.11%)		
occurrences (all)	1		
Gastrointestinal disorders			
CONSTIPATION			
subjects affected / exposed	2 / 90 (2.22%)		
occurrences (all)	2		
DIARRHOEA			
alternative assessment type: Systematic			
subjects affected / exposed	25 / 90 (27.78%)		
occurrences (all)	25		
VOMITING			
alternative assessment type: Systematic			
subjects affected / exposed	20 / 90 (22.22%)		
occurrences (all)	20		
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 90 (2.22%)		
occurrences (all)	2		
NASAL CONGESTION			
subjects affected / exposed	4 / 90 (4.44%)		
occurrences (all)	4		
RHINORRHOEA			
subjects affected / exposed	3 / 90 (3.33%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
DERMATITIS DIAPER			
subjects affected / exposed	1 / 90 (1.11%)		
occurrences (all)	1		

DRY SKIN subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0		
ECZEMA subjects affected / exposed occurrences (all)	7 / 90 (7.78%) 7		
RASH subjects affected / exposed occurrences (all)	8 / 90 (8.89%) 8		
RASH PAPULAR subjects affected / exposed occurrences (all)	1 / 90 (1.11%) 1		
Psychiatric disorders EATING DISORDER alternative assessment type: Systematic subjects affected / exposed occurrences (all)	38 / 90 (42.22%) 38		
Infections and infestations BRONCHIOLITIS subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0		
CROUP INFECTIOUS subjects affected / exposed occurrences (all)	2 / 90 (2.22%) 2		
LOWER RESPIRATORY TRACT INFECTION subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0		
NASOPHARYNGITIS subjects affected / exposed occurrences (all)	14 / 90 (15.56%) 14		
ORAL CANDIDIASIS subjects affected / exposed occurrences (all)	0 / 90 (0.00%) 0		
OTITIS MEDIA subjects affected / exposed occurrences (all)	4 / 90 (4.44%) 4		

RHINITIS			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences (all)	0		
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	20 / 90 (22.22%)		
occurrences (all)	20		
VIRAL INFECTION			
subjects affected / exposed	0 / 90 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 July 2004	A telephone call to be performed during the 6-month follow-up after LPLV, remove OPV vaccine in the UK routine infant vaccination, the administration of diphtheria, tetanus, whole cell pertussis, H influenzae type b vaccine, and poliomyelitis vaccine was replaced by diphtheria, tetanus, acellular pertussis, H influenzae type b, inactivated polio vaccine.
26 October 2004	Two new study groups were added to the study design.
30 November 2004	to get confirmatory data on the final vaccine formulation without adjuvant
09 May 2005	the criterion for visit 5 was updated.
22 June 2005	this amendment was implemented to reassess the use f a booster dose in the UK arm.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported