



Clinical trial results:

A Phase II, open (partially double-blind), randomized, controlled dose-range study to evaluate the immunogenicity, reactogenicity and safety of four different formulations of GlaxoSmithKline (GSK) Biologicals' meningococcal serogroups A, C, W-135, Y tetanus toxoid conjugate (MenACWY-TT) vaccine versus MenC-CRM197 conjugate vaccine or MENCEVAX ACWY when given as one dose to children aged 12 to 14 months and 3 to 5 years old.

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2004-003768-32
Trial protocol	AT
Global end of trial date	16 February 2007

Results information

Result version number	v2
This version publication date	11 June 2016
First version publication date	15 February 2015
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Data correction due to a system error in EudraCT – Results

Trial information

Trial identification

Sponsor protocol code	103533, 103534
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00196976
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
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Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 November 2007
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 February 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Based on the immune response induced one month post vaccination, to select the best of four different formulations of GSK Biologicals' MenACWY-TT conjugate vaccine when given as one single dose to healthy children aged 12-14 months and 3-5 years.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 March 2005
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Greece: 358
Country: Number of subjects enrolled	Austria: 103
Worldwide total number of subjects	461
EEA total number of subjects	461

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	201

months)	
Children (2-11 years)	260
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Period 1

Period 1 title	Primary Study
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

The primary study was a partially double-blind, randomized (1:1:1:1:1), controlled multi-centre study with 5 groups with balanced allocation.

The Formulations 1, 2 & 3 of the candidate Mencevax vaccine (Forms 1, 2 and 3) were administered in a double-blind manner with respect to each other, while Formulation 4 was administered in a single-blind manner.

Arms

Are arms mutually exclusive?	Yes
Arm title	12-14 months of age Formulation 1 Group

Arm description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	12-14 months of age Formulation 2 Group
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Arm description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Arm type	Experimental
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Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	12-14 months of age Formulation 3 Group
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Arm description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm's deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	12-14 months of age Formulation 4 Group
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Arm description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm's deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	12-14 months of age Control Group
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Arm description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of Pfizer's Meningitec conjugate vaccine, intramuscularly into the left arm's deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Arm type	Active comparator
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Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	MenC, Pfizer`s (formerly Wyeth) MenC-CRM conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose of MenC was administered intramuscularly into the left deltoid region	
Arm title	3-5 years of age Formulation 1 Group
Arm description:	
This group received formulation 1 of MenACWY-TT vaccine. Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).	
Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals` meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.	
Arm title	3-5 years of age Formulation 2 Group
Arm description:	
Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).	
Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals` meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.	
Arm title	3-5 years of age Formulation 3 Group
Arm description:	
Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).	
Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals` meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.	
Arm title	3-5 years of age Formulation 4 Group

Arm description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK Biologicals' meningococcal serogroups A, C, W-135, Y-tetanus toxoid conjugate vaccine.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	3-5 years of age Control Group
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Arm description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of Mencevax ACWY vaccine, subcutaneously into the left upper arm, during this primary vaccination study (103533).

Arm type	Active comparator
Investigational medicinal product name	Mencevax ACWY
Investigational medicinal product code	
Other name	MenACWY, GSK Biologicals' meningococcal A, C, W-135, Y plain polysaccharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

1 dose of MenACWY was administered subcutaneously into the left upper arm

Number of subjects in period 1	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group
	Started	39	41
Completed	38	40	37
Not completed	1	1	4
Consent withdrawn by subject	1	-	1
Others	-	-	2
Protocol violation	-	1	1
Migrated from study area	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	12-14 months of age Formulation 4 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group
	Started	40	40
Completed	39	37	52
Not completed	1	3	2
Consent withdrawn by subject	1	2	1
Others	-	-	-

Protocol violation	-	-	-
Migrated from study area	-	-	-
Lost to follow-up	-	1	1

Number of subjects in period 1	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Started	50	52	52
Completed	50	49	52
Not completed	0	3	0
Consent withdrawn by subject	-	-	-
Others	-	-	-
Protocol violation	-	-	-
Migrated from study area	-	1	-
Lost to follow-up	-	2	-

Number of subjects in period 1	3-5 years of age Control Group
Started	52
Completed	51
Not completed	1
Consent withdrawn by subject	1
Others	-
Protocol violation	-
Migrated from study area	-
Lost to follow-up	-

Period 2

Period 2 title	Booster Study
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	12-14 months of age Formulation 1 Group

Arm description:

This group received received formulation 1 of MenACWY-TT vaccine.

Arm type	Experimental
Investigational medicinal product name	MenACWY-TT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	12-14 months of age Control Group
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose was administered

Arm title	3-5 years of age Formulation 1 Group
Arm description:	
This group received formulation 1 of MenACWY-TT vaccine.	
Arm type	Experimental
Investigational medicinal product name	MenACWY-TT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY-TT vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	3-5 years of age Control Group
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose was administered

Number of subjects in period 2 ^[1]	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group
	Started	33	32
Completed	31	30	45
Not completed	2	2	0
Consent withdrawn by subject	1	-	-
Lost to follow-up	1	2	-

Number of subjects in period 2^[1]	3-5 years of age Control Group
Started	43
Completed	43
Not completed	0
Consent withdrawn by subject	-
Lost to follow-up	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all the subjects completing the Primary study came back for the Booster phase follow-up.

Baseline characteristics

Reporting groups

Reporting group title	12-14 months of age Formulation 1 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 2 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 3 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 4 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Control Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of Pfizer`s Meningitec conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	3-5 years of age Formulation 1 Group
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Reporting group description:

This group received formulation 1 of MenACWY-TT vaccine.

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 2 Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 3 Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 4 Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Control Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of Mencevax ACWY vaccine, subcutaneously into the left upper arm, during this primary vaccination study (103533).

Reporting group values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group
Number of subjects	39	41	41
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: months			
arithmetic mean	12.5	12.8	12.8
standard deviation	± 0.82	± 0.86	± 0.86
Gender categorical Units: Subjects			
Female	15	15	17
Male	24	26	24

Reporting group values	12-14 months of age Formulation 4 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group
Number of subjects	40	40	54
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			

Age continuous Units: months arithmetic mean standard deviation	12.9 ± 0.83	12.8 ± 0.79	48.1 ± 7.12
Gender categorical Units: Subjects			
Female	24	19	21
Male	16	21	33

Reporting group values	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Number of subjects	50	52	52
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: months arithmetic mean standard deviation	48 ± 7.22	47.8 ± 7.01	48 ± 7.78
Gender categorical Units: Subjects			
Female	16	23	27
Male	34	29	25

Reporting group values	3-5 years of age Control Group	Total	
Number of subjects	52	461	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: months arithmetic mean standard deviation	47.7 ± 7.15	-	

Gender categorical			
Units: Subjects			
Female	27	204	
Male	25	257	

End points

End points reporting groups

Reporting group title	12-14 months of age Formulation 1 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 2 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 3 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Formulation 4 Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	12-14 months of age Control Group
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Reporting group description:

Healthy male and female toddlers (T) between, and including, 12 to 14 months of age at the time of the first vaccination, were administered one dose of Pfizer`s Meningitec conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533). In accordance with local immunization policy, one dose of a diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

Reporting group title	3-5 years of age Formulation 1 Group
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Reporting group description:

This group received formulation 1 of MenACWY-TT vaccine.

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 1 (Form1) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 2 Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 2 (Form2) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 3 Group
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Reporting group description:

Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 3 (Form3) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).

Reporting group title	3-5 years of age Formulation 4 Group
Reporting group description: Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of formulation 4 (Form4) of the Nimenrix conjugate vaccine, intramuscularly into the left arm`s deltoid region, during this primary vaccination study (103533).	
Reporting group title	3-5 years of age Control Group
Reporting group description: Healthy male and female children (C) between, and including, 3 to 5 years of age at the time of the first vaccination, were administered one dose of Mencevax ACWY vaccine, subcutaneously into the left upper arm, during this primary vaccination study (103533).	
Reporting group title	12-14 months of age Formulation 1 Group
Reporting group description: This group received received formulation 1 of MenACWY-TT vaccine.	
Reporting group title	12-14 months of age Control Group
Reporting group description: -	
Reporting group title	3-5 years of age Formulation 1 Group
Reporting group description: This group received formulation 1 of MenACWY-TT vaccine.	
Reporting group title	3-5 years of age Control Group
Reporting group description: -	

Primary: Number of subjects with an immune response to the serum bactericidal assay meningococcal serogroup A using rabbit complement (rSBA-MenA), rSBA-MenC, rSBA-MenW-135, rSBA-MenY

End point title	Number of subjects with an immune response to the serum bactericidal assay meningococcal serogroup A using rabbit complement (rSBA-MenA), rSBA-MenC, rSBA-MenW-135, rSBA-MenY ^[1]
End point description: A responder was defined as follows: - for initially seronegative subjects (antibody titers < 1:8 for rSBA-Men), a subject achieving a post-vaccination rSBA-Men antibody titer of 1:32; - for initially seropositive subjects (antibody titers ≥ 1:8 for rSBA-Men), a subject having a 4-fold increase in rSBA-Men antibody titer from pre to post vaccination	
End point type	Primary
End point timeframe: One month after the first vaccine dose	

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: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Formulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	36	29	35
Units: Subjects				
rSBA-MenA (N=33,34,26,31,31,45,45,44,50,40)	30	32	26	27
rSBA-MenC (N=32,34,29,34,32,50,48,46,49,42)	30	32	26	33

rSBA-MenW-135 (N=35,36,28,35,33,47,47,46,48,43)	34	36	27	35
rSBA-MenY (N=36,35,29,34,33,48,48,46,50,43)	33	34	26	34

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	50	48	46
Units: Subjects				
rSBA-MenA (N=33,34,26,31,31,45,45,44,50,40)	6	41	38	41
rSBA-MenC (N=32,34,29,34,32,50,48,46,49,42)	30	45	44	44
rSBA-MenW-135 (N=35,36,28,35,33,47,47,46,48,43)	3	46	44	46
rSBA-MenY (N=36,35,29,34,33,48,48,46,50,43)	3	46	47	45

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	43		
Units: Subjects				
rSBA-MenA (N=33,34,26,31,31,45,45,44,50,40)	42	36		
rSBA-MenC (N=32,34,29,34,32,50,48,46,49,42)	46	34		
rSBA-MenW-135 (N=35,36,28,35,33,47,47,46,48,43)	48	36		
rSBA-MenY (N=36,35,29,34,33,48,48,46,50,43)	47	34		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:8
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	30	35
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	23	22	19	21
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	5	2	2	5
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	17	19	12	13
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	23	17	16	19
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	36	38	30	34
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	36	38	28	35
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	35	38	30	35
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	35	38	29	35

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	51	48	48
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	20	41	42	40
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	3	16	8	17
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	15	34	24	25
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	22	37	42	39
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	23	50	47	48
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	34	50	47	47
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	15	50	48	48
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	25	51	48	48

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	47	39		
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	12	14		
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	36	27		
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	42	36		
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	50	43		
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	49	43		
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	50	44		
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	50	44		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers \geq 1:128.
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	30	35
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	19	19	13	19
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	3	0	0	3
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	8	9	4	4

rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	17	11	9	12
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	36	38	29	34
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	35	34	26	31
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	35	38	29	35
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	35	37	29	34

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	51	48	48
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	17	41	39	40
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	1	9	4	5
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	8	19	11	9
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	17	29	37	32
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	20	49	47	48
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	27	49	46	45
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	9	50	48	48
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	18	51	48	48

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: Subjects				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	46	37		
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	7	5		
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	15	12		
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	33	30		
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	50	43		
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	48	39		

rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	49	42		
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	50	43		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	30	35
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	84.2 (39.3 to 180.1)	77.3 (32.9 to 181.6)	68.4 (30.1 to 155.3)	76 (33.8 to 170.8)
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	6.9 (4.1 to 11.5)	4.5 (3.8 to 5.2)	4.6 (3.8 to 5.7)	6.6 (4.2 to 10.2)
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	19.8 (10.7 to 36.9)	21.1 (11.5 to 38.6)	14.5 (7.7 to 27.3)	12.1 (7.1 to 20.6)
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	57.7 (27.5 to 121.3)	24.4 (12 to 49.7)	32.4 (14.3 to 73)	32.9 (15.9 to 68.3)
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	6648 (4787.3 to 9231.9)	5406.8 (3961.5 to 7379.4)	6225.2 (3510.2 to 11040.2)	3928.6 (2851.5 to 5412.4)
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	656.4 (483 to 892)	495.7 (334.6 to 734.4)	477.2 (245.1 to 929.4)	464.3 (324.4 to 664.5)
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	2781.4 (1647 to 4697.2)	3447.5 (2484.8 to 4783.3)	2545 (1522.2 to 4254.9)	3260.8 (2342.1 to 4539.8)
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	2599.9 (1531.8 to 4412.7)	2150.9 (1486.2 to 3112.9)	1920.9 (1014.2 to 3638.2)	3544.7 (2480.2 to 5065.9)

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1	3-5 years of age Formulation 2	3-5 years of age Formulation 3
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		Group	Group	Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	51	48	48
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	69.1 (28.1 to 169.9)	359.7 (212 to 610.4)	367.2 (222.1 to 607)	375.9 (227.4 to 621.2)
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	5.3 (3.8 to 7.3)	12.5 (7.6 to 20.5)	7.4 (4.7 to 11.6)	11.8 (7.5 to 18.5)
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	18 (9.7 to 33.6)	45.8 (27.9 to 75.2)	22.3 (12.7 to 39)	23.7 (14.2 to 39.7)
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	52.8 (25.5 to 109.5)	98.7 (54.9 to 177.5)	181.9 (112.1 to 295.3)	146.8 (86.2 to 250.1)
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	125.9 (53.1 to 298.3)	7469.5 (5468.8 to 10202.1)	7569.7 (6044 to 9480.6)	13668.3 (11274.3 to 16570.6)
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	404.5 (222.5 to 735.4)	967.6 (672 to 1393.3)	1115 (746.4 to 1665.7)	1738.8 (1159.7 to 2607)
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	21.7 (10.5 to 44.9)	4317.4 (3114.8 to 5984.3)	3856.5 (3153.4 to 4716.4)	5262.1 (4417.8 to 6267.7)
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	75.6 (38.1 to 150.1)	5249.1 (4107.9 to 6707.4)	5150.5 (4149.8 to 6392.6)	5896.3 (4686.4 to 7418.5)

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenA, PRE (N=33,34,27,32,34,46,46,44,50,41)	465.2 (307.2 to 704.4)	427.4 (280.3 to 651.7)		
rSBA-MenC, PRE (N=32,34,30,34,32,50,48,47,49,42)	8.9 (5.7 to 14.1)	11.9 (7 to 20.2)		
rSBA-MenW-135,PRE(N=35,36,29,35,34,47,47,46,48)	44.6 (28.1 to 71)	31.5 (18 to 55)		
rSBA-MenY, PRE (N=36,35,30,34,34,48,48,46,50,43)	140.6 (82.8 to 238.9)	123.6 (73.3 to 208.6)		
rSBA-MenA, M1 (N=36,38,30,34,32,50,47,48,50,43)	4878 (4002.5 to 5944.9)	4556.8 (3598 to 5771.1)		
rSBA-MenC, M1 (N=36,38,29,35,35,51,48,47,50,44)	1197.6 (765 to 1874.7)	378.3 (257.2 to 556.5)		
rSBA-MenW-135, M1(N=36,38,30,35,34,51,48,48,50,44)	4556.1 (3576.6 to 5803.7)	912.7 (659.1 to 1264.1)		
rSBA-MenY, M1 (N=36,38,30,35,34,51,48,48,50,44)	7548.4 (6116.1 to 9316.2)	1527.3 (1110.8 to 2099.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$

End point title	Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	31	35
Units: Number				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	1	2	0	1
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	1	1	0	1
Anti-PSW-135, PRE (N=34,35,30,33,33,51,47,48,50,44)	1	0	1	1
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	2	0	2	1
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	35	36	30	34
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	33	38	30	35
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	34	36	30	35
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	34	37	30	34

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	51	47	48
Units: Number				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0	10	4	6
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	1	3	4	1
Anti-PSW-135, PRE (N=34,35,30,33,33,51,47,48,50,44)	0	1	4	2

Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	1	2	4	2
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	2	48	45	48
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	34	49	45	48
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	0	48	45	48
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	2	49	45	46

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: Number				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	9	10		
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	1	2		
Anti-PSW-135, PRE(N=34,35,30,33,33,51,47,48,50,44)	0	1		
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	1	1		
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	48	44		
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	48	44		
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	48	44		
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	48	44		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 2.0 $\mu\text{g/mL}$

End point title	Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 2.0 $\mu\text{g/mL}$
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	31	35
Units: Subjects				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0	0	0	0
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0	0	0	0
Anti-PSW-135, PRE(N=34,35,30,33,33,51,47,48,50,44)	0	0	0	0
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0	0	0	1
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	35	35	30	25
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	33	37	29	34
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	33	27	23	32
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	34	34	27	33

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	51	47	48
Units: Subjects				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0	1	1	0
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0	2	2	0
Anti-PSW-135, PRE(N=34,35,30,33,33,51,47,48,50,44)	0	0	1	0
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0	1	2	0
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	0	48	44	47
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	33	44	45	45
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	0	41	31	41
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	0	46	40	39

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		

Units: Subjects				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	2	5		
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0	2		
Anti-PSW-135, PRE(N=34,35,30,33,33,51,47,48,50,44)	0	0		
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0	0		
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	34	40		
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	47	44		
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	39	39		
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	47	42		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations

End point title	Anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations
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End point description:

End point type	Secondary
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End point timeframe:

Prior to (PRE) and one month after (M1) the first vaccine dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	38	31	35
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0.16 (0.14 to 0.18)	0.16 (0.14 to 0.19)	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.17)
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0.16 (0.14 to 0.17)	0.16 (0.14 to 0.17)	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.16)
Anti-PSW-135, PRE(N=34,35,30,33,33,51,47,48,50,44)	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.17)	0.15 (0.15 to 0.16)
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0.16 (0.14 to 0.18)	0.15 (0.15 to 0.15)	0.16 (0.15 to 0.17)	0.16 (0.14 to 0.2)
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	30.65 (19.83 to 47.38)	22.09 (16.35 to 29.84)	34.68 (21.7 to 55.42)	4.03 (2.72 to 5.98)
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	10.67 (7.47 to 15.23)	11.23 (8.75 to 14.4)	12.91 (8.83 to 18.88)	10.74 (8.43 to 13.68)

Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	7.52 (4.97 to 11.36)	3.12 (2.3 to 4.22)	3.62 (2.31 to 5.68)	7.09 (5.19 to 9.7)
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	10.86 (7.41 to 15.92)	6.71 (5.12 to 8.8)	6.01 (4 to 9.03)	13.38 (9.48 to 18.89)

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	51	47	48
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0.15 (0.15 to 0.15)	0.2 (0.17 to 0.25)	0.17 (0.15 to 0.2)	0.17 (0.15 to 0.19)
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0.16 (0.14 to 0.17)	0.18 (0.15 to 0.22)	0.18 (0.15 to 0.23)	0.16 (0.14 to 0.17)
Anti-PSW-135, PRE (N=34,35,30,33,33,51,47,48,50,44)	0.15 (0.15 to 0.15)	0.15 (0.15 to 0.16)	0.17 (0.15 to 0.2)	0.16 (0.15 to 0.17)
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0.15 (0.15 to 0.16)	0.16 (0.14 to 0.18)	0.19 (0.15 to 0.24)	0.16 (0.15 to 0.17)
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	0.17 (0.14 to 0.2)	20.01 (14.53 to 27.56)	12.62 (8.74 to 18.22)	24.69 (19.14 to 31.85)
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	11.99 (9.26 to 15.53)	6.33 (4.81 to 8.34)	7.76 (5.76 to 10.44)	7.71 (6.05 to 9.83)
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	0.15 (0.15 to 0.15)	4.76 (3.4 to 6.66)	3.2 (2.33 to 4.39)	3.85 (2.85 to 5.21)
Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	0.16 (0.15 to 0.17)	9.41 (6.66 to 13.31)	6.59 (4.7 to 9.25)	5.75 (4.23 to 7.81)

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, PRE (N=33,32,30,27,31,51,46,47,49,43)	0.21 (0.17 to 0.26)	0.25 (0.18 to 0.35)		
Anti-PSC, PRE (N=32,33,30,30,29,51,46,47,50,43)	0.15 (0.15 to 0.16)	0.18 (0.14 to 0.22)		
Anti-PSW-135, PRE (N=34,35,30,33,33,51,47,48,50,44)	0.15 (0.15 to 0.15)	0.16 (0.14 to 0.17)		
Anti-PSY, PRE (N=34,36,30,32,34,51,47,48,50,44)	0.15 (0.15 to 0.16)	0.15 (0.15 to 0.16)		
Anti-PSA, M1 (N=36,36,31,34,30,48,46,48,49,44)	3.63 (2.62 to 5.04)	13.79 (9.04 to 21.02)		
Anti-PSC, M1 (N=34,38,31,35,34,49,46,48,49,44)	7.78 (5.83 to 10.38)	14.44 (11.32 to 18.42)		
Anti-PSW-135, M1 (N=35,37,31,35,34,50,46,48,49,44)	4.99 (3.7 to 6.73)	7.93 (5.39 to 11.66)		

Anti-PSY, M1 (N=35,37,31,34,32,50,46,46,49,44)	11.7 (8.39 to 16.32)	18.96 (13.68 to 26.29)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-tetanus (anti-T) antibody titers \geq 0.1 IU/mL

End point title	Number of subjects with anti-tetanus (anti-T) antibody titers \geq 0.1 IU/mL
End point description:	
End point type	Secondary
End point timeframe:	
Prior to (PRE) and one month after (M1) the first vaccine dose	

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	37	30	35
Units: Subjects				
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	34	36	30	32
Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	36	37	30	35

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	51	48	48
Units: Subjects				
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	33	49	47	46
Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	34	48	47	48

End point values	3-5 years of age Formulation 4	3-5 years of age Control Group		

Subject group type	Group		
	Reporting group	Reporting group	
Number of subjects analysed	50	44	
Units: Subjects			
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	48	43	
Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	50	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-T antibody concentrations

End point title	Anti-T antibody concentrations
End point description:	
End point type	Secondary
End point timeframe:	
Prior to (PRE) and one month after (M1) the first vaccine dose	

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	37	30	35
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	1.007 (0.671 to 1.51)	1.159 (0.814 to 1.65)	1.203 (0.871 to 1.662)	1.293 (0.826 to 2.023)
Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	7.559 (5.04 to 11.335)	5.353 (3.832 to 7.477)	8.094 (4.855 to 13.492)	7.675 (4.783 to 12.315)

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	51	48	48
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	0.792 (0.578 to 1.084)	1.426 (0.94 to 2.164)	1.312 (0.935 to 1.841)	1.232 (0.849 to 1.788)

Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	0.696 (0.52 to 0.932)	17.284 (11.812 to 25.292)	15.823 (11.728 to 21.348)	19.369 (13.226 to 28.363)
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End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	44		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-T, PRE (N=35,36,30,33,34,51,48,48,50,44)	1.18 (0.823 to 1.694)	1.083 (0.742 to 1.58)		
Anti-T, M1 (N=36,37,30,35,35,49,47,48,50,44)	15.957 (11.767 to 21.639)	1.231 (0.833 to 1.82)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of toddlers with solicited local symptoms

End point title	Number of toddlers with solicited local symptoms ^[2]
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End point description:

The 2 doses were as follows:

1st dose of the Meningococcal vaccine (Men Vacc)

2nd dose of the DTPA-containing vaccine (DTPA)

End point type	Secondary
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End point timeframe:

During the 8-day (Days 0-7) post-vaccination period after each dose and overall

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: The analysis was only performed on subjects aged between 12 to 14 months of age.

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	39	40
Units: Subjects				
Pain, Men Vacc (N=38,41,39,40,39)	4	8	3	6
Redness, Men Vacc (N=38,41,39,40,39)	9	12	10	9
Swelling, Men Vacc (N=38,41,39,40,39)	1	6	7	6
Pain, DTPA (N=38,39,37,39,37)	3	10	6	7
Redness, DTPA (N=38,39,37,39,37)	7	13	9	8
Swelling, DTPA (N=38,39,37,39,37)	3	7	9	7

End point values	12-14 months of age Control Group			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Subjects				
Pain, Men Vacc (N=38,41,39,40,39)	4			
Redness, Men Vacc (N=38,41,39,40,39)	11			
Swelling, Men Vacc (N=38,41,39,40,39)	4			
Pain, DTPA (N=38,39,37,39,37)	6			
Redness, DTPA (N=38,39,37,39,37)	7			
Swelling, DTPA (N=38,39,37,39,37)	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of children with solicited local symptoms

End point title	Number of children with solicited local symptoms ^[3]
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End point description:

End point type	Secondary
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End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

Notes:

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

Justification: The analysis was only performed on subjects aged between 3 to 5 years of age.

End point values	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	50	50	52
Units: Subjects				
Pain	10	11	9	11
Redness	9	11	10	9
Swelling	7	9	8	10

End point values	3-5 years of age Control Group			
Subject group type	Reporting group			
Number of subjects analysed	51			

Units: Subjects				
Pain	13			
Redness	7			
Swelling	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of toddlers with solicited general symptoms

End point title	Number of toddlers with solicited general symptoms ^[4]
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End point description:

End point type	Secondary
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End point timeframe:

During the 8-day (Days 0-7) post-vaccination period following each study vaccine

Notes:

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

Justification: The analysis was only performed on subjects aged between 12 to 14 months of age.

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	41	39	40
Units: Subjects				
Drowsiness, Men Vacc (N=38;41;39;40;39)	1	5	4	4
Fever (Rectal), Men Vacc (N=38;41;39;40;39)	5	8	8	3
Irritability, Men Vacc (N=38;41;39;40;39)	4	9	6	5
Loss of appetite, Men Vacc (N=38;41;39;40;39)	1	6	5	3
Drowsiness, DTPA (N=38;39;37;39;37)	2	2	3	7
Fever (Rectal), DTPA (N=38;39;37;39;37)	4	5	5	5
Irritability, DTPA (N=38;39;37;39;37)	6	7	3	9
Loss of appetite, DTPA (N=38;39;37;39;37)	4	3	2	6

End point values	12-14 months of age Control Group			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Subjects				
Drowsiness, Men Vacc (N=38;41;39;40;39)	5			

Fever (Rectal), Men Vacc (N=38;41;39;40;39)	5			
Irritability, Men Vacc (N=38;41;39;40;39)	5			
Loss of appetite, Men Vacc (N=38;41;39;40;39)	6			
Drowsiness, DTPA (N=38;39;37;39;37)	3			
Fever (Rectal), DTPA (N=38;39;37;39;37)	8			
Irritability, DTPA (N=38;39;37;39;37)	5			
Loss of appetite, DTPA (N=38;39;37;39;37)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of children with solicited general symptoms

End point title	Number of children with solicited general symptoms ^[5]
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End point description:

End point type	Secondary
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End point timeframe:

During the 8-day (Days 0-7) post-vaccination period

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The analysis was only performed on subjects aged between 3 to 5 years of age.

End point values	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	50	50	52
Units: Subjects				
Drowsiness	4	2	0	5
Fever (Rectal)	4	4	3	3
Irritability	2	4	2	4
Loss of appetite	2	3	2	6

End point values	3-5 years of age Control Group			
Subject group type	Reporting group			
Number of subjects analysed	51			
Units: Subjects				
Drowsiness	4			
Fever (Rectal)	3			
Irritability	7			

Loss of appetite	3			
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Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$ ^[6]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Formulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	44	37
Units: Subjects				
rSBA-MenA, M1 (N=31,27,43,36)	31	18	43	36
rSBA-MenC, M1 (N=31,30,44,37)	31	29	43	36
rSBA-MenW-135, M1 (N=31,29,44,37)	30	11	43	37
rSBA-MenY, M1 (N=31,29,44,37)	30	20	44	37
rSBA-MenA, M12 (N=23,25,39,33)	23	20	39	33
rSBA-MenC, M12 (N=31,29,41,32)	29	25	40	22
rSBA-MenW-135, M12 (N=31,27,41,35)	30	11	41	31
rSBA-MenY, M12 (N=31,29,41,37)	31	23	41	36

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:128$.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:128$. ^[7]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	44	37
Units: Subjects				
rSBA-MenA, M1 (N=31,27,43,36)	31	14	42	36
rSBA-MenC, M1 (N=31,30,44,37)	31	23	42	34
rSBA-MenW-135, M1 (N=31,29,44,37)	30	6	43	35
rSBA-MenY, M1 (N=31,29,44,37)	30	13	44	36
rSBA-MenA, M12 (N=23,25,39,33)	23	19	39	32
rSBA-MenC, M12 (N=31,29,41,32)	13	15	27	10
rSBA-MenW-135, M12 (N=31,27,41,35)	27	6	41	27
rSBA-MenY, M12 (N=31,29,41,37)	30	17	40	32

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers ^[8]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	44	37
Units: Titers				
geometric mean (confidence interval 95%)				

rSBA-MenA, M1 (N=31,27,43,36)	6577.8 (4606.7 to 9392.4)	84.9 (32.4 to 222.8)	6565.3 (4616.3 to 9337.2)	4649.5 (3572.8 to 6050.8)
rSBA-MenC, M1 (N=31,30,44,37)	660.4 (484.4 to 900.3)	440.2 (227.1 to 853.1)	893.6 (600.3 to 1330.3)	416.2 (270.5 to 640.5)
rSBA-MenW-135, M1 (N=31,29,44,37)	2523.5 (1433.1 to 4443.7)	17.2 (7.9 to 37.8)	3893.6 (2671.2 to 5675.6)	1004.4 (690.4 to 1461.2)
rSBA-MenY, M1 (N=31,29,44,37)	2483.9 (1363.8 to 4524.1)	57.7 (27.1 to 123.2)	4808.5 (3653 to 6329.6)	1641.1 (1131.2 to 2380.9)
rSBA-MenA, M12 (N=23,25,39,33)	2369.1 (1642 to 3418.2)	179.3 (76.1 to 422.9)	2356.7 (1786.7 to 3108.4)	1134.3 (767.8 to 1675.5)
rSBA-MenC, M12 (N=31,29,41,32)	110.2 (60.6 to 200.7)	122 (59 to 252.2)	172.5 (117.7 to 252.9)	41.7 (22 to 79.2)
rSBA-MenW-135, M12 (N=31,27,41,35)	541.8 (305.5 to 961)	18.9 (8.4 to 42.9)	1322.2 (978.3 to 1786.8)	181.7 (104.6 to 315.8)
rSBA-MenY, M12 (N=31,29,41,37)	740.3 (493.4 to 1110.9)	110.6 (51.6 to 237.1)	1400.8 (1008.8 to 1945.1)	347.2 (228.2 to 528.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$ ^[9]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[9] - 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: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	43	37
Units: Subjects				
Anti-PSA, M1 (N=31,25,41,37)	30	1	41	37
Anti-PSC, M1 (N=29,30,42,37)	28	30	42	37
Anti-PSW-135, M1 (N=30,29,43,37)	29	0	41	37
Anti-PSY, M1 (N=30,27,43,37)	29	2	42	37
Anti-PSA, M12 (N=27,22,38,36)	22	2	34	34
Anti-PSC, M12 (N=27,27,39,37)	13	18	18	36
Anti-PSW-135, M12 (N=25,21,37,34)	25	3	34	32

Anti-PSY, M12 (N=26,21,37,35)	26	3	34	35
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Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 2.0 \mu\text{g/mL}$

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 2.0 \mu\text{g/mL}$ ^[10]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[10] - 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: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	43	37
Units: Subjects				
Anti-PSA, M1 (N=31,25,41,37)	30	0	41	33
Anti-PSC, M1 (N=29,30,42,37)	28	29	37	37
Anti-PSW-135, M1 (N=30,29,43,37)	28	0	34	32
Anti-PSY, M1 (N=30,27,43,37)	29	0	39	35
Anti-PSA, M12 (N=27,22,38,36)	10	0	12	22
Anti-PSC, M12 (N=27,27,39,37)	2	4	0	24
Anti-PSW-135, M12 (N=25,21,37,34)	6	2	10	23
Anti-PSY, M12 (N=26,21,37,35)	15	1	19	30

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations

End point title	Anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ^[11]
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End point description:

End point type	Secondary
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End point timeframe:

At one month (M1) and 12 months (M12) post primary vaccination

Notes:

[11] - 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: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	30	43	37
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSA, M1 (N=31,25,41,37)	32.72 (20.12 to 53.22)	0.17 (0.14 to 0.2)	18.29 (12.86 to 26.01)	13 (8.19 to 20.63)
Anti-PSC, M1 (N=29,30,42,37)	11.25 (7.48 to 16.93)	12.43 (9.28 to 16.65)	5.64 (4.21 to 7.57)	14.5 (11.01 to 19.1)
Anti-PSW-135, M1 (N=30,29,43,37)	6.65 (4.29 to 10.3)	0.15 (0.15 to 0.15)	4.23 (2.94 to 6.09)	8.17 (5.19 to 12.86)
Anti-PSY, M1 (N=30,27,43,37)	10.37 (6.74 to 15.94)	0.16 (0.15 to 0.17)	8.07 (5.79 to 11.24)	18.12 (12.41 to 26.46)
Anti-PSA, M12 (N=27,22,38,36)	1.25 (0.68 to 2.3)	0.17 (0.14 to 0.21)	1.32 (0.9 to 1.95)	4.43 (2.55 to 7.7)
Anti-PSC, M12 (N=27,27,39,37)	0.39 (0.23 to 0.66)	0.54 (0.34 to 0.86)	0.28 (0.22 to 0.36)	2.9 (1.94 to 4.35)
Anti-PSW-135, M12 (N=25,21,37,34)	1.36 (1.06 to 1.74)	0.21 (0.14 to 0.32)	1.11 (0.79 to 1.57)	3.16 (1.87 to 5.34)
Anti-PSY, M12 (N=26,21,37,35)	2.36 (1.75 to 3.18)	0.21 (0.14 to 0.33)	1.84 (1.2 to 2.82)	6.9 (4.51 to 10.54)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$ and $\geq 1:128$

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titers $\geq 1:8$ and $\geq 1:128$
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End point description:

End point type	Secondary
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End point timeframe:

Before (PRE = at Month 12) and post (M13 = at Month 13) booster vaccination.

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	24		
Units: Subjects				
rSBA-MenA \geq 1:8, PRE (N=20,21)	20	17		
rSBA-MenC \geq 1:8, PRE (N=27,24)	25	20		
rSBA-MenW-135 \geq 1:8, PRE (N=27,23)	26	9		
rSBA-MenY \geq 1:8, PRE (N=27,24)	27	18		
rSBA-MenA \geq 1:128, PRE (N=20,21)	20	16		
rSBA-MenC \geq 1:128, PRE (N=27,24)	10	12		
rSBA-MenW-135 \geq 1:128, PRE (N=27,23)	23	4		
rSBA-MenY \geq 1:128, PRE (N=27,24)	26	14		
rSBA-MenA \geq 1:8, M13 (N=6,20)	6	19		
rSBA-MenC \geq 1:8, M13 (N=25,24)	25	24		
rSBA-MenW-135 \geq 1:8, M13 (N=25,24)	25	21		
rSBA-MenY \geq 1:8, M13 (N=25,24)	25	22		
rSBA-MenA \geq 1:128, M13 (N=6,20)	6	19		
rSBA-MenC \geq 1:128, M13 (N=25,24)	24	24		
rSBA-MenW-135 \geq 1:128, M13 (N=25,24)	25	18		
rSBA-MenY \geq 1:128, M13 (N=25,24)	25	20		

Statistical analyses

No statistical analyses for this end point

Secondary: rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titers
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End point description:

End point type	Secondary
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End point timeframe:

Before (PRE = at Month 12) and post (M13 = at Month 13) booster vaccination.

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	24		
Units: Titers				
geometric mean (confidence interval 95%)				

rSBA-MenA, PRE (N=20,21)	2163.4 (1436.6 to 3257.9)	175.7 (70.5 to 437.8)		
rSBA-MenC, PRE (N=27,24)	82.5 (50.3 to 135.4)	102.5 (47.7 to 220.3)		
rSBA-MenW-135, PRE (N=27,23)	436 (243.7 to 780.2)	15.5 (7 to 34.3)		
rSBA-MenY, PRE (N=27,24)	634.5 (420 to 958.3)	93.6 (38.4 to 228.1)		
rSBA-MenA, M13 (N=6,20)	3695.2 (1535.2 to 8894.7)	984.6 (479.7 to 2021.2)		
rSBA-MenC, M13 (N=25,24)	7067.4 (4070.7 to 12270.3)	9209.3 (5153.4 to 16457.5)		
rSBA-MenW-135, M13 (N=25,24)	5642.4 (3360 to 9475.4)	255.6 (110.1 to 593.6)		
rSBA-MenY, M13 (N=25,24)	3337.7 (2013.7 to 5532.1)	323.8 (153.6 to 682.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$ and $\geq 2.0 \mu\text{g/mL}$

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations $\geq 0.3 \mu\text{g/mL}$ and $\geq 2.0 \mu\text{g/mL}$
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End point description:

End point type	Secondary
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End point timeframe:

Before (PRE) and 1 Month post (M13) booster vaccination

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	23		
Units: Subjects				
Anti-PSA $\geq 0.3 \mu\text{g/mL}$, PRE (N=24,19)	19	1		
Anti-PSC $\geq 0.3 \mu\text{g/mL}$, PRE (N=24,23)	11	15		
Anti-PSW-135 $\geq 0.3 \mu\text{g/mL}$, PRE (N=23,18)	23	2		
Anti-PSY $\geq 0.3 \mu\text{g/mL}$, PRE (N=24,18)	24	2		
Anti-PSA $\geq 2.0 \mu\text{g/mL}$, PRE (N=24,19)	7	0		
Anti-PSC $\geq 2.0 \mu\text{g/mL}$, PRE (N=24,23)	1	3		
Anti-PSW-135 $\geq 2.0 \mu\text{g/mL}$, PRE (N=23,18)	5	1		

Anti-PSY \geq 2.0 $\mu\text{g/mL}$, PRE (N=24,18)	14	0		
Anti-PSA \geq 0.3 $\mu\text{g/mL}$, M13 (N=26,21)	26	19		
Anti-PSC \geq 0.3 $\mu\text{g/mL}$, M13 (N=26,22)	25	22		
Anti-PSW-135 \geq 0.3 $\mu\text{g/mL}$, M13 (N=25,21)	25	18		
Anti-PSY \geq 0.3 $\mu\text{g/mL}$, M13 (N=25,21)	25	20		
Anti-PSA \geq 2.0 $\mu\text{g/mL}$, M13 (N=26,21)	25	13		
Anti-PSC \geq 2.0 $\mu\text{g/mL}$, M13 (N=26,22)	25	22		
Anti-PSW-135 \geq 2.0 $\mu\text{g/mL}$, M13 (N=25,21)	24	9		
Anti-PSY \geq 2.0 $\mu\text{g/mL}$, M13 (N=25,21)	24	12		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations

End point title	Anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations
End point description:	
End point type	Secondary
End point timeframe:	Before (PRE) and 1 Month post (M13) booster vaccination

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	23		
Units: $\mu\text{g/mL}$				
geometric mean (confidence interval 95%)				
Anti-PSA, PRE (N=24,19)	0.98 (0.56 to 1.69)	0.16 (0.14 to 0.18)		
Anti-PSA, POST (N=26,21)	0.32 (0.22 to 0.48)	0.5 (0.31 to 0.8)		
Anti-PSC, PRE (N=24,23)	1.33 (1.02 to 1.72)	0.19 (0.13 to 0.27)		
Anti-PSC, POST (N=26,22)	2.34 (1.69 to 3.24)	0.19 (0.13 to 0.26)		
Anti-PSW-135, PRE (N=23,18)	25.67 (17.39 to 37.91)	3.1 (1.34 to 7.2)		
Anti-PSW-135, POST (N=25,21)	11.63 (7.73 to 17.5)	15.23 (10.66 to 21.77)		
Anti-PSY, PRE (N=24,18)	56.94 (35.87 to 90.38)	1.34 (0.63 to 2.88)		
Anti-PSY, POST (N=25,21)	79.03 (52.06 to 119.97)	4.19 (2 to 8.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms

End point title | Number of subjects with solicited local symptoms

End point description:

End point type | Secondary

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period following booster dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	30		
Units: Subjects				
Pain	1	0		
Redness	3	3		
Swelling	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms

End point title | Number of subjects with solicited general symptoms

End point description:

End point type | Secondary

End point timeframe:

During the 8-day (Days 0-7) post-vaccination period following booster dose

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	30		
Units: Subjects				
Any Drowsiness	3	5		
Any Fever (Rectally)	5	3		
Any Irritability	4	5		
Any Loss of appetite	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited Adverse Events (AEs) after Men Vacc primary vaccination

End point title	Number of subjects with unsolicited Adverse Events (AEs) after Men Vacc primary vaccination
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End point description:

End point type	Secondary
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End point timeframe:

Within 31 days (Days 0-30) after the primary meningococcal vaccination

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	41	40
Units: Subjects				
Any AEs	11	16	5	8

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	54	50	52
Units: Subjects				
Any AEs	14	6	12	7

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	52		
Units: Subjects				
Any AEs	5	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs after DTPA primary vaccination

End point title	Number of subjects with unsolicited AEs after DTPA primary vaccination ^[12]
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End point description:

End point type	Secondary
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End point timeframe:

Within 31 days (Days 0-30) after the DTPa-IPV/Hib or DTPa- HBV-IP/Hib vaccination during primary vaccination

Notes:

[12] - 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: The analysis was only performed on subjects who had received DTPA vaccination (Infanrix or Infanrix hexa vaccines).

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	40	37	40
Units: Subjects				
Any AEs	5	8	5	5

End point values	12-14 months of age Control Group			
Subject group type	Reporting group			
Number of subjects analysed	39			
Units: Subjects				
Any AEs	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs

End point title	Number of subjects with unsolicited AEs
End point description:	
End point type	Secondary
End point timeframe:	
Within 31 days (Days 0-30) after the booster vaccination	

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	32		
Units: Subjects				
Any AEs	3	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with Serious Adverse Events (SAEs)

End point title	Number (%) of subjects with Serious Adverse Events (SAEs)
End point description:	
End point type	Secondary
End point timeframe:	
During the primary vaccination study	

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group	12-14 months of age Formulation 4 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	41	41	40
Units: Subjects				
Any SAEs	1	1	1	1

End point values	12-14 months of age Control Group	3-5 years of age Formulation 1	3-5 years of age Formulation 2	3-5 years of age Formulation 3
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		Group	Group	Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	40	54	50	52
Units: Subjects				
Any SAEs	1	0	0	0

End point values	3-5 years of age Formulation 4 Group	3-5 years of age Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	52		
Units: Subjects				
Any SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with SAEs

End point title	Number (%) of subjects with SAEs
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End point description:

End point type	Secondary
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End point timeframe:

Since the last study contact in the primary study to the end of the booster study

End point values	12-14 months of age Formulation 1 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group	3-5 years of age Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	32	45	43
Units: Subjects				
Any SAEs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: during the 8-day (Days 0-7) post-vaccination period. Unsolicited AEs: within 31 days (Days 0-30) after each vaccination. SAEs: from the beginning of the primary study up to the end of the booster study.

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	9.0
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Reporting groups

Reporting group title	12-14 months of age Formulation 1 Group
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Reporting group description: -

Reporting group title	12-14 months of age Formulation 2 Group
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Reporting group description: -

Reporting group title	12-14 months of age Formulation 3 Group
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Reporting group description: -

Reporting group title	12-14 months of age Formulation 4 Group
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Reporting group description: -

Reporting group title	12-14 months of age Control Group
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Reporting group description: -

Reporting group title	3-5 years of age Formulation 1 Group
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Reporting group description: -

Reporting group title	3-5 years of age Formulation 2 Group
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Reporting group description: -

Reporting group title	3-5 years of age Formulation 3 Group
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Reporting group description: -

Reporting group title	3-5 years of age Formulation 4 Group
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Reporting group description: -

Reporting group title	3-5 years of age Control Group
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Reporting group description: -

Serious adverse events	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 39 (2.56%)	1 / 41 (2.44%)	1 / 41 (2.44%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Skin and subcutaneous tissue disorders			
Maculo-papular rash			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 41 (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			
Laryngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 39 (0.00%)	1 / 41 (2.44%)	0 / 41 (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
Bronchiolitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 39 (2.56%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	12-14 months of age Formulation 4 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 54 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Skin and subcutaneous tissue disorders			
Maculo-papular rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 54 (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
Infections and infestations			
Laryngitis			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 54 (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
Acute bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 54 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 54 (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	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Skin and subcutaneous tissue disorders			
Maculo-papular rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (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			
Laryngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (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
Acute bronchitis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (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	3-5 years of age Control Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 52 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Skin and subcutaneous tissue disorders			
Maculo-papular rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Laryngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 52 (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	12-14 months of age Formulation 1 Group	12-14 months of age Formulation 2 Group	12-14 months of age Formulation 3 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 39 (28.21%)	16 / 41 (39.02%)	10 / 41 (24.39%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed	4 / 39 (10.26%)	10 / 41 (24.39%)	6 / 41 (14.63%)
occurrences (all)	4	10	6
Redness			
subjects affected / exposed	9 / 39 (23.08%)	13 / 41 (31.71%)	10 / 41 (24.39%)
occurrences (all)	9	13	10
Swelling			
subjects affected / exposed	3 / 39 (7.69%)	7 / 41 (17.07%)	9 / 41 (21.95%)
occurrences (all)	3	7	9
Drowsiness			
subjects affected / exposed	3 / 39 (7.69%)	5 / 41 (12.20%)	4 / 41 (9.76%)
occurrences (all)	3	5	4
Fever			
subjects affected / exposed	5 / 39 (12.82%)	8 / 41 (19.51%)	8 / 41 (19.51%)
occurrences (all)	5	8	8
Irritability			
subjects affected / exposed	6 / 39 (15.38%)	9 / 41 (21.95%)	6 / 41 (14.63%)
occurrences (all)	6	9	6
Loss of appetite			
subjects affected / exposed	4 / 39 (10.26%)	6 / 41 (14.63%)	5 / 41 (12.20%)
occurrences (all)	4	6	5
Pyrexia			
alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	1 / 39 (2.56%) 1	0 / 41 (0.00%) 0	0 / 41 (0.00%) 0
Gastrointestinal disorders Diarrhea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	0 / 41 (0.00%) 0	0 / 41 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	3 / 41 (7.32%) 3	0 / 41 (0.00%) 0
Skin and subcutaneous tissue disorders Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 39 (0.00%) 0	3 / 41 (7.32%) 3	0 / 41 (0.00%) 0
Infections and infestations Rhinitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Pharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Gastroenteritis viral alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) Bronchitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	3 / 39 (7.69%) 3 1 / 39 (2.56%) 1 2 / 39 (5.13%) 2 0 / 39 (0.00%) 0	2 / 41 (4.88%) 2 0 / 41 (0.00%) 0 0 / 41 (0.00%) 0 0 / 41 (0.00%) 0	0 / 41 (0.00%) 0 0 / 41 (0.00%) 0 0 / 41 (0.00%) 0 0 / 41 (0.00%) 0

Non-serious adverse events	12-14 months of age Formulation 4 Group	12-14 months of age Control Group	3-5 years of age Formulation 1 Group
Total subjects affected by non-serious adverse events subjects affected / exposed	9 / 40 (22.50%)	14 / 40 (35.00%)	10 / 54 (18.52%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed	7 / 40 (17.50%)	6 / 40 (15.00%)	10 / 54 (18.52%)
occurrences (all)	7	6	10
Redness			
subjects affected / exposed	9 / 40 (22.50%)	11 / 40 (27.50%)	9 / 54 (16.67%)
occurrences (all)	9	11	9
Swelling			
subjects affected / exposed	7 / 40 (17.50%)	4 / 40 (10.00%)	7 / 54 (12.96%)
occurrences (all)	7	4	7
Drowsiness			
subjects affected / exposed	7 / 40 (17.50%)	5 / 40 (12.50%)	4 / 54 (7.41%)
occurrences (all)	7	5	4
Fever			
subjects affected / exposed	5 / 40 (12.50%)	8 / 40 (20.00%)	4 / 54 (7.41%)
occurrences (all)	5	8	4
Irritability			
subjects affected / exposed	9 / 40 (22.50%)	5 / 40 (12.50%)	2 / 54 (3.70%)
occurrences (all)	9	5	2
Loss of appetite			
subjects affected / exposed	6 / 40 (15.00%)	6 / 40 (15.00%)	2 / 54 (3.70%)
occurrences (all)	6	6	2
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	1 / 54 (1.85%)
occurrences (all)	0	2	1
Gastrointestinal disorders			
Diarrhea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 54 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			

Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	1 / 40 (2.50%) 1	1 / 54 (1.85%) 1
Skin and subcutaneous tissue disorders Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 54 (0.00%) 0
Infections and infestations Rhinitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	3 / 40 (7.50%) 3	0 / 54 (0.00%) 0
Pharyngitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	2 / 40 (5.00%) 2	0 / 54 (0.00%) 0
Gastroenteritis viral alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 54 (0.00%) 0
Bronchitis alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	2 / 40 (5.00%) 2	1 / 54 (1.85%) 1

Non-serious adverse events	3-5 years of age Formulation 2 Group	3-5 years of age Formulation 3 Group	3-5 years of age Formulation 4 Group
Total subjects affected by non-serious adverse events subjects affected / exposed	12 / 50 (24.00%)	10 / 52 (19.23%)	11 / 52 (21.15%)
General disorders and administration site conditions Pain subjects affected / exposed occurrences (all)	11 / 50 (22.00%) 11	9 / 52 (17.31%) 9	11 / 52 (21.15%) 11
Redness			

subjects affected / exposed occurrences (all)	11 / 50 (22.00%) 11	10 / 52 (19.23%) 10	9 / 52 (17.31%) 9
Swelling subjects affected / exposed occurrences (all)	9 / 50 (18.00%) 9	8 / 52 (15.38%) 8	10 / 52 (19.23%) 10
Drowsiness subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	0 / 52 (0.00%) 0	5 / 52 (9.62%) 5
Fever subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4	3 / 52 (5.77%) 3	3 / 52 (5.77%) 3
Irritability subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 4	2 / 52 (3.85%) 2	4 / 52 (7.69%) 4
Loss of appetite subjects affected / exposed occurrences (all)	3 / 50 (6.00%) 3	2 / 52 (3.85%) 2	6 / 52 (11.54%) 6
Pyrexia alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 52 (0.00%) 0	0 / 52 (0.00%) 0
Gastrointestinal disorders Diarrhea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 52 (0.00%) 0	1 / 52 (1.92%) 1
Respiratory, thoracic and mediastinal disorders Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 52 (1.92%) 1	0 / 52 (0.00%) 0
Skin and subcutaneous tissue disorders Rash alternative assessment type: Non-systematic			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 52 (0.00%) 0	0 / 52 (0.00%) 0
Infections and infestations			
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 50 (2.00%)	1 / 52 (1.92%)	0 / 52 (0.00%)
occurrences (all)	1	1	0
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	3-5 years of age Control Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 52 (25.00%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	13 / 52 (25.00%)		
occurrences (all)	13		
Redness			
subjects affected / exposed	7 / 52 (13.46%)		
occurrences (all)	7		
Swelling			
subjects affected / exposed	4 / 52 (7.69%)		
occurrences (all)	4		
Drowsiness			

<p>subjects affected / exposed occurrences (all)</p> <p>Fever</p> <p>subjects affected / exposed occurrences (all)</p> <p>Irritability</p> <p>subjects affected / exposed occurrences (all)</p> <p>Loss of appetite</p> <p>subjects affected / exposed occurrences (all)</p> <p>Pyrexia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed occurrences (all)</p>	<p>4 / 52 (7.69%) 4</p> <p>3 / 52 (5.77%) 3</p> <p>7 / 52 (13.46%) 7</p> <p>3 / 52 (5.77%) 3</p> <p>0 / 52 (0.00%) 0</p>		
<p>Gastrointestinal disorders</p> <p>Diarrhea</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed occurrences (all)</p>	<p>0 / 52 (0.00%) 0</p>		
<p>Respiratory, thoracic and mediastinal disorders</p> <p>Cough</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed occurrences (all)</p>	<p>0 / 52 (0.00%) 0</p>		
<p>Skin and subcutaneous tissue disorders</p> <p>Rash</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed occurrences (all)</p>	<p>0 / 52 (0.00%) 0</p>		
<p>Infections and infestations</p> <p>Rhinitis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed occurrences (all)</p> <p>Pharyngitis</p>	<p>1 / 52 (1.92%) 1</p>		

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences (all)	0		
Gastroenteritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences (all)	0		
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 February 2005	Due to logistic changes, the vial containing the formulation without spacer of the candidate MenACWY-TT vaccine differs slightly in appearance from the vials containing the 3 different formulations with spacer. Therefore the three different formulations with spacer of the candidate MenACWY-TT vaccine (F1, F2 and F3) will be administered in a double-blind manner with respect to each other, however they will be single-blinded with respect to the formulation without spacer (F4). The requirements for regulatory reporting of SAEs have been changed to comply with new regulations following the European Union Clinical Trial Directive, and to align with GSK Biologicals standard operating procedures.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported