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.

Summary

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

Results information

Result version number	v4 (current)
This version publication date	17 October 2020
First version publication date	15 February 2015
Version creation reason	• Correction of full data set Correction of errors in safety section.

Trial information

Trial identification

Sponsor protocol code	103533, 103534

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

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 months)	201
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 Nimenrix 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 diphteria, tetanus and acellular pertussis (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, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	DTPa-IPV/Hib, GSK Biologicals` combined diphteria, tetanus, acellular pertusis, inactivated poliomyelitis and conjugated Haemophilus influenzae type b vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix vaccine was administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib, GSK Biologicals` combined diphteria,tetanus,acellular pertussis,inactivated poliomyelitis,hepatitis B and conjugated Haem. influenzae type

Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix Hexa vaccine was administered by intramuscular injection into the left thigh.

Arm title	12-14 months of age Formulation 2 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 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 diphteria, 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, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	DTPa-IPV/Hib, GSK Biologicals` combined diphteria, tetanus, acellular pertusis, inactivated poliomyelitis and conjugated Haemophilus influenzae type b vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix vaccine was administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib, GSK Biologicals` combined diphteria,tetanus,acellular pertussis,inactivated poliomyelitis,hepatitis B and conjugated Haem. influenzae type
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix Hexa vaccine was administered by intramuscular injection into the left thigh.

Arm title	12-14 months of age Formulation 3 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 3 (Form 3) 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, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	DTPa-IPV/Hib, GSK Biologicals` combined diphteria, tetanus, acellular pertusis, inactivated poliomyelitis and conjugated Haemophilus influenzae type b vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix vaccine was administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib, GSK Biologicals` combined diphteria,tetanus,acellular pertussis,inactivated poliomyelitis,hepatitis B and conjugated Haem. influenzae type
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix Hexa vaccine was administered by intramuscular injection into the left thigh.

Arm title	12-14 months of age Formulation 4 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 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, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	DTPa-IPV/Hib, GSK Biologicals` combined diphteria, tetanus, acellular pertusis, inactivated poliomyelitis and conjugated Haemophilus influenzae type b vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix vaccine was administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib, GSK Biologicals` combined diphteria,tetanus,acellular pertussis,inactivated poliomyelitis,hepatitis B and conjugated Haem. influenzae type
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix Hexa vaccine was administered by intramuscular injection into the left thigh.

Arm title	12-14 months of age Control 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 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 diphteria, 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
Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	MenC, Pfizer`s (formerly Wyeth) MenC-CRM197 conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Meningitec vaccine was administered intramuscularly into the left deltoid region.

Investigational medicinal product name	Infanrix
Investigational medicinal product code	
Other name	DTPa-IPV/Hib, GSK Biologicals` combined diphteria, tetanus, acellular pertusis, inactivated poliomyelitis and conjugated Haemophilus influenzae type b vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix vaccine was administered by intramuscular injection into the left thigh.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-HBV-IPV/Hib, GSK Biologicals` combined diphteria,tetanus,acellular pertussis,inactivated poliomyelitis,hepatitis B and conjugated Haem. influenzae type
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Infanrix Hexa vaccine was administered by intramuscular injection into the left thigh.

Arm title	3-5 years of age Formulation 1 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 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, GSK134612A, 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:

Nimenrix 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, GSK134612A, 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:

Nimenrix 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, GSK134612A, 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:

Nimenrix 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, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	3-5 years of age Control 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 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 polysachharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Mencevax ACWY vaccine 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	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	54
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 Booster 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, who 12 months after being primed with formulation 1 (Form1) of the Nimenrix conjugate vaccine, additionally received 1/5 dose of Mencevax ACWY vaccine intramuscularly into the left deltoid region, during the booster study (103534).

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Investigational medicinal product name	Mencevax ACWY
Investigational medicinal product code	
Other name	MenACWY, GSK Biologicals` meningococcal A, C, W-135, Y plain polysachharide vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1/5 dose of Mencevax ACWY vaccine was administered intramuscularly into the left deltoid region.

Arm title	12-14 months of age Booster Control 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, who 12 months after
being primed with Pfizer`s Meningitec conjugate vaccine, additionally received 1/5 dose of Mencevax ACWY vaccine intramuscularly into the left deltoid region, during the booster study (103534).

Arm type	Active comparator
Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	MenC, Pfizer`s (formerly Wyeth) MenC-CRM197 conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Meningitec vaccine was administered intramuscularly into the left deltoid region.

Investigational medicinal product name	Mencevax ACWY
Investigational medicinal product code	
Other name	MenACWY, GSK Biologicals` meningococcal A, C, W-135, Y plain polysachharide vaccine
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use

Dosage and administration details:

1/5 dose of Mencevax ACWY vaccine was administered intramuscularly into the left deltoid region.

Arm title	3-5 years of age Booster 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, who 12 months after being
primed with formulation 1 (Form1) of the Nimenrix conjugate vaccine, did not receive any booster vaccination.

Arm type	Experimental
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	MenACWY-TT, GSK134612A, 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:

Nimenrix vaccine formulations were administered by intramuscular injection into the left deltoid region.

Arm title	3-5 years of age Booster Control 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, who 12 months after being
primed with Pfizer`s Meningitec conjugate vaccine, did not receive any booster vaccination.

Arm type	Active comparator
Investigational medicinal product name	Meningitec
Investigational medicinal product code	
Other name	MenC, Pfizer`s (formerly Wyeth) MenC-CRM197 conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Meningitec vaccine was administered intramuscularly into the left deltoid region.

Number of subjects in period 2[1]	12-14 months of age Booster Group	12-14 months of age Booster Control Group	3-5 years of age Booster Group
Started	33	32	45
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 Booster 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

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 diphteria, tetanus and acellular pertussis (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

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 diphteria, 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

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 (Form 3) 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

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

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 diphteria, 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

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 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

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

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 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
Race Units: Subjects			
White/Caucasian	38	40	40
Arabic/north african	1	0	1
East/south east asian	0	1	0
Black	0	0	0

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	12.9	12.8	48.1
standard deviation	± 0.83	± 0.79	± 7.12
Gender categorical Units: Subjects			
Female	24	19	21
Male	16	21	33
Race Units: Subjects			
White/Caucasian	38	39	53
Arabic/north african	0	1	1
East/south east asian	1	0	0
Black	1	0	0

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	48	47.8	48
standard deviation	± 7.22	± 7.01	± 7.78
Gender categorical Units: Subjects			
Female	16	23	27
Male	34	29	25
Race Units: Subjects			
White/Caucasian	50	50	50
Arabic/north african	0	2	1
East/south east asian	0	0	0
Black	0	0	1

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	47.7		
standard deviation	± 7.15	-	
Gender categorical Units: Subjects			
Female	27	204	
Male	25	257	
Race Units: Subjects			
White/Caucasian	51	449	
Arabic/north african	0	7	
East/south east asian	0	2	
Black	1	3	

End points

End points reporting groups

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

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 diphteria, tetanus and acellular pertussis (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

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 diphteria, 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

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 (Form 3) 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

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

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 diphteria, 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

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 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

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

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 Booster Group

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, who 12 months after being primed with formulation 1 (Form1) of the Nimenrix conjugate vaccine, additionally received 1/5 dose of Mencevax ACWY vaccine intramuscularly into the left deltoid region, during the booster study (103534).

Reporting group title	12-14 months of age Booster Control Group

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, who 12 months after
being primed with Pfizer`s Meningitec conjugate vaccine, additionally received 1/5 dose of Mencevax ACWY vaccine intramuscularly into the left deltoid region, during the booster study (103534).

Reporting group title	3-5 years of age Booster 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, who 12 months after being
primed with formulation 1 (Form1) of the Nimenrix conjugate vaccine, did not receive any booster vaccination.

Reporting group title	3-5 years of age Booster 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, who 12 months after being
primed with Pfizer`s Meningitec conjugate vaccine, did not receive any booster vaccination.

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 to serum bactericidal assay meningococcal serogroups A, C, W and Y, using rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) was defined as follows: -for initially seronegative subjects (antibody titres < 1:8 for rSBA-Men), a subject achieving a post-vaccination rSBA-Men antibody titre of ≥ 1:32; - for initially seropositive subjects (antibody titres ≥ 1:8 for rSBA-Men), a subject having a ≥ 4-fold increase in rSBA-Men antibody titre 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 titres ≥ 1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:8

End point description:

A seroprotected subject against meningococcal serogroups rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY assessed, was defined as having antibody titres greater than or equal to (≥) 1:8.

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	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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:128.

End point description:

A seropositive subject for meningococcal serogroups rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-Y assessed, was defined as having antibody titres greater than or equal to (≥) 1:128.

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	38	30	35
Units: Sbjects				
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: Sbjects				
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: Sbjects				
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 titres

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres

End point description:

Antibody titers against meningococcal serogroups A, C, W-135 and Y (MenA, MenC, MenW-135 and MenY) have been assessed, using rabbit complement and expressed as geometric mean titres (GMTs).

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	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 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: 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 ≥ 0.3 µg/mL

End point title	Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 0.3 µg/mL

End point description:

A seropositive subject for meningococcal polysaccharide A (PSA), C (PSC), W-135 (PSW-135) and Y (PSY) assessed, was defined as having antibody (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) concentrations greater than or equal to (≥) the cut-off value of 0.3 micrograms per millilitre (µg/mL). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA).

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	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 µg/mL

End point title	Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 2.0 µg/mL

End point description:

A seroprotected subject for meningococcal polysaccharide A (PSA), C (PSC), W-135 (PSW-135) and Y (PSY) assessed, was defined as having antibody (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) concentrations greater than or equal to (≥) the value of 2.0 micrograms per millilitre (µg/mL). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA).

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	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

End point description:

The meningococcal polysaccharides assessed included polysaccharide A (anti-PSA), polysaccharide B (anti-PSB), polysaccharide W-135 (anti-PSW-135) and polysaccharide Y (anti-PSY). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per millilitre (µg/mL).

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	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)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-tetanus (anti-T) antibody concentrations ≥ 0.1 IU/mL

End point title	Number of subjects with anti-tetanus (anti-T) antibody concentrations ≥ 0.1 IU/mL

End point description:

A seropositive subject for anti-tetanus was defined as having antibody concentrations greater than or equal to (≥) the cut-off value of 0.1 international units per millilitre (IU/mL). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA).

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 Group	3-5 years of age Control Group		
Subject group type	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:

Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) method, presented as geometric mean concentrations (GMCs) and expressed in international units per millilitre (IU/mL).

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)

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]

End point description:

The toddlers subgroup received 2 primary vaccine doses, as follows: first dose of a meningococcal vaccine (Men) and second dose of a diphtheria, tetanus and acellular pertusis-containing vaccine (DTPa). Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade.

End point type	Secondary

End point timeframe:

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

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]

End point description:

The children subgroup received one dose of the meningococcal vaccine. Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade.

End point type	Secondary

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]

End point description:

The toddlers subgroup received 2 primary vaccine doses, as follows: first dose of a meningococcal vaccine (Men) and second dose of a diphtheria, tetanus and acellular pertusis-containing vaccine (DTPa). Assessed solicited general symptoms included drowsiness, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], irritability and loss of appetite. Any = incidence of a particular symptom regardless of intensity or relationship to vaccination.

End point type	Secondary

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]

End point description:

The children subgroup received one primary meningococcal vaccine dose. Assessed solicited general symptoms included drowsiness, fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)], irritability and loss of appetite. Any = incidence of a particular symptom regardless of intensity or relationship to vaccination.

End point type	Secondary

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			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:8

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:8[6]

End point description:

A seroprotected subject against meningococcal serogroups rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY assessed, was defined as having antibody titres greater than or equal to (≥) 1:8.

End point type	Secondary

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 titres ≥ 1:128.

End point title	Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY titres ≥ 1:128.[7]

End point description:

A seropositive subject for meningococcal serogroups rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-Y assessed, was defined as having antibody titres greater than or equal to (≥) 1:128.

End point type	Secondary

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 (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	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 titres

End point title	rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres[8]

End point description:

Antibody titres against meningococcal serogroups A, C, W-135 and Y (MenA, MenC, MenW-135 and MenY) have been assessed, using rabbit complement and expressed as geometric mean titres (GMTs).

End point type	Secondary

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 ≥ 0.3 µg/mL

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 0.3 µg/mL[9]

End point description:

A seropositive subject for meningococcal polysaccharide A (PSA), C (PSC), W-135 (PSW-135) and Y (PSY) assessed, was defined as having antibody (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) concentrations greater than or equal to (≥) the cut-off value of 0.3 micrograms per millilitre (µg/mL). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA).

End point type	Secondary

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

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 ≥ 2.0 µg/mL

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 2.0 µg/mL[10]

End point description:

A seroprotected subject for meningococcal polysaccharide A (PSA), C (PSC), W-135 (PSW-135) and Y (PSY) assessed, was defined as having antibody (anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY) concentrations greater than or equal to (≥) the value of 2.0 micrograms per millilitre (µg/mL). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA).

End point type	Secondary

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]

End point description:

The meningococcal polysaccharides assessed included polysaccharide A (anti-PSA), polysaccharide B (anti-PSB), polysaccharide W-135 (anti-PSW-135) and polysaccharide Y (anti-PSY). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per millilitre (µg/mL).

End point type	Secondary

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 ≥ 1:8 and ≥ 1:128

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

End point description:

A seropositive subject for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY was defined as a vaccinated subject with antibody titres greater than or equal to (≥) 1:128, while for a seroprotected subject, titres were ≥1:8.

End point type	Secondary

End point timeframe:

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

End point values	12-14 months of age Booster Group	12-14 months of age Booster Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	27	24		
Units: Subjects				
rSBA-MenA ≥ 1:8, PRE (N=20,21)	20	17		
rSBA-MenC ≥ 1:8, PRE (N=27,24)	25	20		
rSBA-MenW-135 ≥ 1:8, PRE (N=27,23)	26	9		
rSBA-MenY ≥ 1:8, PRE (N=27,24)	27	18		

rSBA-MenA ≥ 1:128, PRE (N=20,21)	20	16		
rSBA-MenC ≥ 1:128, PRE (N=27,24)	10	12		
rSBA-MenW-135 ≥ 1:128, PRE (N=27,23)	23	4		
rSBA-MenY ≥ 1:128, PRE (N=27,24)	26	14		
rSBA-MenA ≥ 1:8, M13 (N=6,20)	6	19		
rSBA-MenC ≥ 1:8, M13 (N=25,24)	25	24		
rSBA-MenW-135 ≥ 1:8, M13 (N=25,24)	25	21		
rSBA-MenY ≥ 1:8, M13 (N=25,24)	25	22		
rSBA-MenA ≥ 1:128, M13 (N=6,20)	6	19		
rSBA-MenC ≥ 1:128, M13 (N=25,24)	24	24		
rSBA-MenW-135 ≥ 1:128, M13 (N=25,24)	25	18		
rSBA-MenY ≥ 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

End point description:

Antibody titres against meningococcal serogroups A, C, W-135 and Y (MenA, MenC, MenW-135 and MenY) have been assessed, using rabbit complement and expressed as geometric mean titres (GMTs).

End point type	Secondary

End point timeframe:

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

End point values	12-14 months of age Booster Group	12-14 months of age Booster 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 ≥ 0.3 µg/mL and ≥ 2.0 µg/mL

End point title	Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 0.3 µg/mL and ≥ 2.0 µg/mL

End point description:

A seropositive subject for anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY was defined as a vaccinated subject with antibody concentrations greater than or equal to (≥) 0.3 micrograms per millilitre (µg/mL), while for a seroprotected subject, antibody concentrations were ≥ 2.0 µg/mL.

End point type	Secondary

End point timeframe:

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

End point values	12-14 months of age Booster Group	12-14 months of age Booster Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	23		
Units: Subjects				
Anti-PSA ≥ 0.3 µg/mL, PRE (N=24,19)	19	1		
Anti-PSC ≥ 0.3 µg/mL, PRE (N=24,23)	11	15		
Anti-PSW-135 ≥ 0.3 µg/mL, PRE (N=23,18)	23	2		
Anti-PSY ≥ 0.3 µg/mL, PRE (N=24,18)	24	2		
Anti-PSA ≥ 2.0 µg/mL, PRE(N=24,19)	7	0		
Anti-PSC ≥ 2.0 µg/mL, PRE (N=24,23)	1	3		
Anti-PSW-135 ≥ 2.0 µg/mL, PRE (N=23,18)	5	1		
Anti-PSY ≥ 2.0 µg/mL, PRE (N=24,18)	14	0		
Anti-PSA ≥ 0.3 µg/mL, M13 (N=26,21)	26	19		
Anti-PSC ≥ 0.3 µg/mL, M13 (N=26,22)	25	22		
Anti-PSW-135 ≥ 0.3 µg/mL, M13 (N=25,21)	25	18		
Anti-PSY ≥ 0.3 µg/mL, M13 (N=25,21)	25	20		
Anti-PSA ≥ 2.0 µg/mL, M13 (N=26,21)	25	13		
Anti-PSC ≥ 2.0 µg/mL, M13 (N=26,22)	25	22		
Anti-PSW-135 ≥ 2.0 µg/mL, M13 (N=25,21)	24	9		

Anti-PSY ≥ 2.0 µg/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:

The meningococcal polysaccharides assessed included polysaccharide A (anti-PSA), polysaccharide B (anti-PSB), polysaccharide W-135 (anti-PSW-135) and polysaccharide Y (anti-PSY). Antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per millilitre (µg/mL).

End point type	Secondary

End point timeframe:

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

End point values	12-14 months of age Booster Group	12-14 months of age Booster Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	23		
Units: µg/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:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade.

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 Booster Group	12-14 months of age Booster 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:

Assessed solicited general symptoms were drowsiness, fever [defined as rectal temperature equal to or above 38.0 degrees Celsius (°C)], irritability and loss of appetite. Any = incidence of a particular symptom regardless of intensity or relationship to vaccination.

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 Booster Group	12-14 months of age Booster 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 primary meningococcal vaccination

End point title	Number of subjects with unsolicited Adverse Events (AEs) after primary meningococcal vaccination

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Secondary

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]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

End point type	Secondary

End point timeframe:

Within 31 days (Days 0-30) post-vaccination with diphteria, tetanus and acellular pertusis-containing vaccine, during the 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:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

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 Booster Group	12-14 months of age Booster 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:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

During the primary vaccination study (Month 0 up to Month 2)

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 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 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

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Secondary

End point timeframe:

Since the last study contact in the primary study to the end of the booster study (Month 2 up to Month 13)

End point values	12-14 months of age Booster Group	12-14 months of age Booster Control Group	3-5 years of age Booster Group	3-5 years of age Booster 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 information

Timeframe for reporting adverse events:

Solicited symptoms reported during the 8-day and unsolicited AEs during the 31-day follow-up period after primary vaccination. SAEs reported during the primary course of the study (Month 0 up to 2). For booster data, refer to the specific endpoints.

Adverse event reporting additional description:

The solicited local and general symptoms were only collected from those subjects who filled in their symptom sheets. Except for the 5 toddlers (T) primary groups, the Total Number (#) of Participants Affected by Other (non-serious) Adverse Events (AEs) is currently populated by the highest value of #Participants affected within other AE's table.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	9.0

Reporting groups

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

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 diphteria, tetanus and acellular pertussis (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

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 diphteria, tetanus and acellular pertussis (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

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 (Form 3) 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

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

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 diphteria, 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

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 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

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

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).

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	20 / 39 (51.28%)	27 / 41 (65.85%)	23 / 41 (56.10%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed[1]	5 / 38 (13.16%)	13 / 41 (31.71%)	8 / 39 (20.51%)
occurrences (all)	5	13	8

Redness			
subjects affected / exposed[2]	12 / 38 (31.58%)	15 / 41 (36.59%)	11 / 39 (28.21%)
occurrences (all)	12	15	11
Swelling			
subjects affected / exposed[3]	4 / 38 (10.53%)	8 / 41 (19.51%)	9 / 39 (23.08%)
occurrences (all)	4	8	9
Drowsiness			
subjects affected / exposed[4]	2 / 38 (5.26%)	6 / 41 (14.63%)	4 / 39 (10.26%)
occurrences (all)	2	6	4
Fever			
subjects affected / exposed[5]	8 / 38 (21.05%)	10 / 41 (24.39%)	10 / 39 (25.64%)
occurrences (all)	8	10	10
Irritability			
subjects affected / exposed[6]	8 / 38 (21.05%)	13 / 41 (31.71%)	6 / 39 (15.38%)
occurrences (all)	8	13	6
Loss of appetite			
subjects affected / exposed[7]	4 / 38 (10.53%)	9 / 41 (21.95%)	5 / 39 (12.82%)
occurrences (all)	4	9	5
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 39 (2.56%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 39 (0.00%)	1 / 41 (2.44%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 39 (0.00%)	3 / 41 (7.32%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Rash			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 39 (0.00%)	3 / 41 (7.32%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Infections and infestations			
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 39 (7.69%)	2 / 41 (4.88%)	0 / 41 (0.00%)
occurrences (all)	3	2	0
Pharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 39 (2.56%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 39 (5.13%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 39 (0.00%)	0 / 41 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	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	24 / 40 (60.00%)	25 / 40 (62.50%)	10 / 54 (18.52%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed[1]	10 / 40 (25.00%)	9 / 39 (23.08%)	10 / 54 (18.52%)
occurrences (all)	10	9	10
Redness			
subjects affected / exposed[2]	11 / 40 (27.50%)	13 / 39 (33.33%)	9 / 54 (16.67%)
occurrences (all)	11	13	9
Swelling			
subjects affected / exposed[3]	9 / 40 (22.50%)	6 / 39 (15.38%)	7 / 54 (12.96%)
occurrences (all)	9	6	7
Drowsiness			

subjects affected / exposed[4]	9 / 40 (22.50%)	7 / 39 (17.95%)	4 / 54 (7.41%)
occurrences (all)	9	7	4
Fever			
subjects affected / exposed[5]	8 / 40 (20.00%)	11 / 39 (28.21%)	4 / 54 (7.41%)
occurrences (all)	8	11	4
Irritability			
subjects affected / exposed[6]	10 / 40 (25.00%)	8 / 39 (20.51%)	2 / 54 (3.70%)
occurrences (all)	10	8	2
Loss of appetite			
subjects affected / exposed[7]	8 / 40 (20.00%)	7 / 39 (17.95%)	2 / 54 (3.70%)
occurrences (all)	8	7	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	0 / 40 (0.00%)	1 / 40 (2.50%)	1 / 54 (1.85%)
occurrences (all)	0	1	1
Skin and subcutaneous tissue disorders			
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 40 (2.50%)	3 / 40 (7.50%)	0 / 54 (0.00%)
occurrences (all)	1	3	0
Pharyngitis			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	0 / 54 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 54 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	1 / 54 (1.85%)
occurrences (all)	1	2	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	11 / 50 (22.00%)	10 / 52 (19.23%)	11 / 52 (21.15%)
General disorders and administration site conditions			
Pain			
subjects affected / exposed[1]	11 / 50 (22.00%)	9 / 52 (17.31%)	11 / 52 (21.15%)
occurrences (all)	11	9	11
Redness			
subjects affected / exposed[2]	11 / 50 (22.00%)	10 / 52 (19.23%)	9 / 52 (17.31%)
occurrences (all)	11	10	9
Swelling			
subjects affected / exposed[3]	9 / 50 (18.00%)	8 / 52 (15.38%)	10 / 52 (19.23%)
occurrences (all)	9	8	10
Drowsiness			
subjects affected / exposed[4]	2 / 50 (4.00%)	0 / 52 (0.00%)	5 / 52 (9.62%)
occurrences (all)	2	0	5
Fever			
subjects affected / exposed[5]	4 / 50 (8.00%)	3 / 52 (5.77%)	3 / 52 (5.77%)
occurrences (all)	4	3	3
Irritability			
subjects affected / exposed[6]	4 / 50 (8.00%)	2 / 52 (3.85%)	4 / 52 (7.69%)
occurrences (all)	4	2	4
Loss of appetite			

subjects affected / exposed[7]	3 / 50 (6.00%)	2 / 52 (3.85%)	6 / 52 (11.54%)
occurrences (all)	3	2	6
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 52 (0.00%)	1 / 52 (1.92%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
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
Skin and subcutaneous tissue disorders			
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	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	0 / 50 (0.00%)	0 / 52 (0.00%)	0 / 52 (0.00%)
occurrences (all)	0	0	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[1]	13 / 52 (25.00%)		
occurrences (all)	13		
Redness			
subjects affected / exposed[2]	7 / 52 (13.46%)		
occurrences (all)	7		
Swelling			
subjects affected / exposed[3]	4 / 52 (7.69%)		
occurrences (all)	4		
Drowsiness			
subjects affected / exposed[4]	4 / 52 (7.69%)		
occurrences (all)	4		
Fever			
subjects affected / exposed[5]	3 / 52 (5.77%)		
occurrences (all)	3		
Irritability			
subjects affected / exposed[6]	7 / 52 (13.46%)		
occurrences (all)	7		
Loss of appetite			
subjects affected / exposed[7]	3 / 52 (5.77%)		
occurrences (all)	3		
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 52 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			

Diarrhea alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	 0 / 52 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Cough alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	 0 / 52 (0.00%) 0		
Skin and subcutaneous tissue disorders Rash alternative assessment type: Non-systematic subjects affected / exposed occurrences (all)	 0 / 52 (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)	 1 / 52 (1.92%) 1 0 / 52 (0.00%) 0 0 / 52 (0.00%) 0 0 / 52 (0.00%) 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Solicited local/general symptoms were tabulated only for subjects with a symptom sheet completed.

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

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

For safety results after booster vaccination (not included in this summary due to a technical limitation), please refer to the respective endpoints or to the safety section detailed at https://www.clinicaltrials.gov/ct2/show/results/NCT00196976.

Notes: