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

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

## Summary

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

**Results information**

| | |
|---|---|
| Result version number | v2 |
| This version publication date | 11 June 2016 |
| First version publication date | 15 February 2015 |
| Version creation reason | • Correction of full data set<br>Data correction due to a system error in EudraCT – Results |

## 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 | 201 |

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

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

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

### Period 1

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

Blinding implementation details:

The primary study was a partially double-blind, randomized (1:1:1:1:1), controlled multi-centre study with 5 groups with balanced allocation.
The Formulations 1, 2 & 3 of the candidate Mencevax vaccine (Forms 1, 2 and 3) were administered in a double-blind manner with respect to each other, while Formulation 4 was administered in a single-blind manner.

### Arms

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

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 12-14 months of age Formulation 2 Group |

Arm description:

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

| | |
|---|---|
| Arm type | Experimental |

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 12-14 months of age Formulation 3 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 12-14 months of age Formulation 4 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 12-14 months of age Control Group |

Arm description:

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

| | |
|---|---|
| Arm type | Active comparator |

| | |
|---|---|
| Investigational medicinal product name | Meningitec |
| Investigational medicinal product code | |
| Other name | MenC, Pfizer`s (formerly Wyeth) MenC-CRM conjguate vaccine |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

1 dose of MenC was administered intramuscularly into the left deltoid region

| | |
|---|---|
| **Arm title** | 3-5 years of age Formulation 1 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 3-5 years of age Formulation 2 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 3-5 years of age Formulation 3 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 3-5 years of age Formulation 4 Group |

Arm description:

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

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

Dosage and administration details:

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

| | |
|---|---|
| **Arm title** | 3-5 years of age Control Group |

Arm description:

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

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

Dosage and administration details:

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

| **Number of subjects in period 1** | 12-14 months of age Formulation 1 Group | 12-14 months of age Formulation 2 Group | 12-14 months of age Formulation 3 Group |
|---|---|---|---|
| Started | 39 | 41 | 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 Formulation 1 Group |

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

1 dose was administered

| **Arm title** | 3-5 years of age Formulation 1 Group |
|---|---|

Arm description:

This group received formulation 1 of MenACWY-TT vaccine.

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

Dosage and administration details:

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

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

Dosage and administration details:

1 dose was administered

| **Number of subjects in period 2[1]** | 12-14 months of age Formulation 1 Group | 12-14 months of age Control Group | 3-5 years of age Formulation 1 Group |
|---|---|---|---|
| Started | 33 | 32 | 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 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.

## 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 diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

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

Reporting group description:

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

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

Reporting group description:

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

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

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 diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

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

Reporting group description:

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

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

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 |

| **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 |

| **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 |

| **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<br>Units: Subjects | | | |
|---|---|---|---|
| Female | 27 | 204 | |
| Male | 25 | 257 | |

## End points

### End points reporting groups

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

Reporting group description:

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

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

Reporting group description:

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

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

Reporting group description:

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

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

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 diphtheria, tetanus and acellular pertusis (Infanrix or Infanrix Hexa) vaccine was also administered intramuscularly into the left thigh, one month after meningococcal vaccination.

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

Reporting group description:

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

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

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 Formulation 1 Group |
|---|---|

Reporting group description:

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

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

Reporting group description: -

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

Reporting group description:

This group received formulation 1 of MenACWY-TT vaccine.

| Reporting group title | 3-5 years of age Control Group |
|---|---|

Reporting group description: -

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

| End point title | Number of subjects with an immune response to the serum bactericidal assay meningococcal serogroup A using rabbit complement (rSBA-MenA), rSBA-MenC, rSBA-MenW-135, rSBA-MenY[1] |
|---|---|

End point description:

A responder was defined as follows:
- for initially seronegative subjects (antibody titers < 1:8 for rSBA-Men), a subject achieving a post-vaccination rSBA-Men antibody titer of 1:32;
- for initially seropositive subjects (antibody titers ≥ 1:8 for rSBA-Men), a subject having a 4-fold increase in rSBA-Men antibody titer from pre to post vaccination

| End point type | Primary |
|---|---|

End point timeframe:

One month after the first vaccine dose

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis was only performed on all subjects of the Control groups and all subjects part of the group with the selected MenACWY-TT formulation (Fromulation 1).

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

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

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

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

### Statistical analyses

No statistical analyses for this end point

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

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

End point timeframe:
Prior to (PRE) and one month after (M1) the first vaccine dose

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

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

| End point values | 12-14 months of age Formulation 1 Group | 12-14 months of age Formulation 2 Group | 12-14 months of age Formulation 3 Group | 12-14 months of age Formulation 4 Group |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 36 | 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 titers**

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

End point description:

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

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

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

| End point values | 12-14 months of age Control Group | 3-5 years of age Formulation 1 | 3-5 years of age Formulation 2 | 3-5 years of age Formulation 3 |
|---|---|---|---|---|

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

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

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with anti-polysaccharide A (PSA), anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 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:

| 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:

| | |
|---|---|
| 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:

| 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 titers ≥ 0.1 IU/mL**

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

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

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

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

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

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

| | 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:

| 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 2 doses were as follows:
1st dose of the Meningococcal vaccine (Men Vacc)
2nd dose of the DTPA-containg vaccine (DTPA)

| End point type | Secondary |
|---|---|

End point timeframe:

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

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on subjects aged between 12 to 14 months of age.

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

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

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of children with solicited local symptoms

| End point title | Number of children with solicited local symptoms[3] |
|---|---|

End point description:

| 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:

| 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:

| 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 titers ≥ 1:8

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

End point description:

| 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 (Fromulation 1).

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

| 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 (Fromulation 1).

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

| 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:

| 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:

| 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:

| 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:

| 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 Formulation 1 Group | 12-14 months of age Control Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 27 | 24 | | |
| Units: Subjects | | | | |
| rSBA-MenA ≥ 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:

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

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

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of subjects with anti-PSA, anti-PSC, anti-PSW-135 and anti-PSY antibody concentrations ≥ 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:

| End point type | Secondary |
|---|---|

End point timeframe:

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

| **End point values** | 12-14 months of age Formulation 1 Group | 12-14 months of age Control Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 26 | 23 | | |
| Units: 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:

| End point type | Secondary |
|---|---|

End point timeframe:

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

| **End point values** | 12-14 months of age Formulation 1 Group | 12-14 months of age Control Group | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 26 | 23 | | |
| Units: 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:

| End point type | Secondary |
|---|---|

End point timeframe:

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

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

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with solicited general symptoms

| End point title | Number of subjects with solicited general symptoms |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

| 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:

| End point type | Secondary |
|---|---|

End point timeframe:

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

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The analysis was only performed on subjects who had received DTPA vaccination (Infanrix or Infanrix hexa vaccines).

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

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

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with unsolicited AEs

| End point title | Number of subjects with unsolicited AEs |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

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

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

## Statistical analyses

No statistical analyses for this end point

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

| End point title | Number (%) of subjects with Serious Adverse Events (SAEs) |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

During the primary vaccination study

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

| End point values | 12-14 months of age Control Group | 3-5 years of age Formulation 1 | 3-5 years of age Formulation 2 | 3-5 years of age Formulation 3 |
|---|---|---|---|---|

| | | Group | Group | Group |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 40 | 54 | 50 | 52 |
| Units: Subjects | | | | |
| Any SAEs | 1 | 0 | 0 | 0 |

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

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number (%) of subjects with SAEs

| End point title | Number (%) of subjects with SAEs |
|---|---|

End point description:

| End point type | Secondary |
|---|---|

End point timeframe:

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

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

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

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

| | |
|---|---|
| Assessment type | Systematic |

### 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: - | |
| Reporting group title | 12-14 months of age Formulation 2 Group |
| Reporting group description: - | |
| Reporting group title | 12-14 months of age Formulation 3 Group |
| Reporting group description: - | |
| Reporting group title | 12-14 months of age Formulation 4 Group |
| Reporting group description: - | |
| Reporting group title | 12-14 months of age Control Group |
| Reporting group description: - | |
| Reporting group title | 3-5 years of age Formulation 1 Group |
| Reporting group description: - | |
| Reporting group title | 3-5 years of age Formulation 2 Group |
| Reporting group description: - | |
| Reporting group title | 3-5 years of age Formulation 3 Group |
| Reporting group description: - | |
| Reporting group title | 3-5 years of age Formulation 4 Group |
| Reporting group description: - | |
| Reporting group title | 3-5 years of age Control Group |

Reporting group description: -

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

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

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

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 40 (0.00%) | 0 / 54 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute bronchitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 40 (0.00%) | 0 / 54 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 40 (0.00%) | 0 / 54 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | 3-5 years of age Formulation 2 Group | 3-5 years of age Formulation 3 Group | 3-5 years of age Formulation 4 Group |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Maculo-papular rash | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Laryngitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute bronchitis | | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 52 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

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

| | | | |
|---|---|---|---|
| subjects affected / exposed | 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%) | 0 / 41 (0.00%) | 0 / 41 (0.00%) |
| occurrences (all) | 0 | 0 | 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 | 9 / 40 (22.50%) | 14 / 40 (35.00%) | 10 / 54 (18.52%) |
| General disorders and administration site conditions | | | |
| Pain | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 6 / 40 (15.00%) | 10 / 54 (18.52%) |
| occurrences (all) | 7 | 6 | 10 |
| Redness | | | |
| subjects affected / exposed | 9 / 40 (22.50%) | 11 / 40 (27.50%) | 9 / 54 (16.67%) |
| occurrences (all) | 9 | 11 | 9 |
| Swelling | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 4 / 40 (10.00%) | 7 / 54 (12.96%) |
| occurrences (all) | 7 | 4 | 7 |
| Drowsiness | | | |
| subjects affected / exposed | 7 / 40 (17.50%) | 5 / 40 (12.50%) | 4 / 54 (7.41%) |
| occurrences (all) | 7 | 5 | 4 |
| Fever | | | |
| subjects affected / exposed | 5 / 40 (12.50%) | 8 / 40 (20.00%) | 4 / 54 (7.41%) |
| occurrences (all) | 5 | 8 | 4 |
| Irritability | | | |
| subjects affected / exposed | 9 / 40 (22.50%) | 5 / 40 (12.50%) | 2 / 54 (3.70%) |
| occurrences (all) | 9 | 5 | 2 |
| Loss of appetite | | | |
| subjects affected / exposed | 6 / 40 (15.00%) | 6 / 40 (15.00%) | 2 / 54 (3.70%) |
| occurrences (all) | 6 | 6 | 2 |
| Pyrexia | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 2 / 40 (5.00%) | 1 / 54 (1.85%) |
| occurrences (all) | 0 | 2 | 1 |
| Gastrointestinal disorders | | | |
| Diarrhea | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 0 / 40 (0.00%) | 0 / 54 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---|---|---|
| Cough | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 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 | 12 / 50 (24.00%) | 10 / 52 (19.23%) | 11 / 52 (21.15%) |
| General disorders and administration site conditions | | | |
| Pain | | | |
| subjects affected / exposed | 11 / 50 (22.00%) | 9 / 52 (17.31%) | 11 / 52 (21.15%) |
| occurrences (all) | 11 | 9 | 11 |
| Redness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 11 / 50 (22.00%) | 10 / 52 (19.23%) | 9 / 52 (17.31%) |
| occurrences (all) | 11 | 10 | 9 |
| Swelling | | | |
| subjects affected / exposed | 9 / 50 (18.00%) | 8 / 52 (15.38%) | 10 / 52 (19.23%) |
| occurrences (all) | 9 | 8 | 10 |
| Drowsiness | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 0 / 52 (0.00%) | 5 / 52 (9.62%) |
| occurrences (all) | 2 | 0 | 5 |
| Fever | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 3 / 52 (5.77%) | 3 / 52 (5.77%) |
| occurrences (all) | 4 | 3 | 3 |
| Irritability | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 2 / 52 (3.85%) | 4 / 52 (7.69%) |
| occurrences (all) | 4 | 2 | 4 |
| Loss of appetite | | | |
| subjects affected / exposed | 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 | 1 / 50 (2.00%) | 1 / 52 (1.92%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Bronchitis | | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 52 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

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

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

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

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported