



Clinical trial results:

Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine Administered Concomitantly With Other Pediatric Vaccines in Healthy Toddlers

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2018-001472-38 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 19 July 2018 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 |
| This version publication date | 08 August 2019 |
| First version publication date | 08 August 2019 |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | MET57 |
|-----------------------|-------|

Additional study identifiers

| | |
|------------------------------------|-----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03205371 |
| WHO universal trial number (UTN) | U1111-1161-2787 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Sanofi Pasteur |
| Sponsor organisation address | Discovery Drive, Swiftwater, PA, United States, 18370-0187 |
| Public contact | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com |
| Scientific contact | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001930-PIP01-16 |
| 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 | 27 February 2019 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 19 July 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To describe the immunogenicity profile of MenACYW conjugate vaccine administered alone or concomitantly with licensed pediatric vaccine(s) ((measles-mumps-rubella vaccine [MMR] +Varicella, diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis, and Haemophilus influenzae type-b Conjugate vaccine [DTaP-IPV-HB-Hib], or pneumococcal Conjugate vaccine [PCV13]).

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 07 November 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | Mexico: 400 |
| Country: Number of subjects enrolled | Russian Federation: 400 |
| Country: Number of subjects enrolled | Korea, Republic of: 213 |
| Country: Number of subjects enrolled | Thailand: 170 |
| Worldwide total number of subjects | 1183 |
| EEA total number of subjects | 0 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 1183 |
| Children (2-11 years) | 0 |

| | |
|---------------------------|---|
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study subjects were enrolled in South Korea, Mexico, the Russian Federation, and Thailand from 07 November 2016 to 13 June 2018.

Pre-assignment

Screening details:

A total of 1183 subjects were enrolled and randomized in the study.

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--|
| Are arms mutually exclusive? | Yes |
| Arm title | South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine |

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 milliliter (mL), intramuscular, single dose on Day 0.

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Measles, Mumps, and Rubella Vaccine |
| Investigational medicinal product code | |
| Other name | M-M-R® II |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

| | |
|--|--------------------------|
| Investigational medicinal product name | Varicella Vaccine |
| Investigational medicinal product code | |
| Other name | VARIVAX |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

| | |
|------------------|--|
| Arm title | South Korea (Group 2): MenACYW Conjugate Vaccine |
|------------------|--|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

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

| | |
|---|--|
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Arm title | South Korea (Group 3): MMR + Varicella Vaccine |
| Arm description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0. | |
| Arm type | Active comparator |
| Investigational medicinal product name | Measles, Mumps, and Rubella Vaccine |
| Investigational medicinal product code | |
| Other name | M-M-R® II |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: 0.5 mL, subcutaneous, single dose on Day 0. | |
| Investigational medicinal product name | Varicella Vaccine |
| Investigational medicinal product code | |
| Other name | VARIVAX |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: 0.5 mL, subcutaneous, single dose on Day 0. | |
| Arm title | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine |
| Arm description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0. | |
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Investigational medicinal product name | Measles, Mumps, and Rubella Vaccine |
| Investigational medicinal product code | |
| Other name | M-M-R® II |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details: 0.5 mL, subcutaneous, single dose on Day 0. | |
| Investigational medicinal product name | Varicella Vaccine |
| Investigational medicinal product code | |
| Other name | VARIVAX |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

| | |
|------------------|--|
| Arm title | Thailand (Group 11): MenACYW Conjugate Vaccine |
|------------------|--|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

| | |
|------------------|--|
| Arm title | Thailand (Group 12): MMR + Varicella Vaccine |
|------------------|--|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.

| | |
|--|-------------------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Measles, Mumps, and Rubella Vaccine |
| Investigational medicinal product code | |
| Other name | M-M-R® II |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

| | |
|--|--------------------------|
| Investigational medicinal product name | Varicella Vaccine |
| Investigational medicinal product code | |
| Other name | VARIVAX |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, single dose on Day 0.

| | |
|------------------|---|
| Arm title | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine |
|------------------|---|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

| | |
|---|--|
| Investigational medicinal product name | DTaP-IPV-HB-Hib: Diphtheria, tetanus, pertussis (acellular), hepatitis B, poliomyelitis (inactivated), and Haemophilus influenzae type b conjugate vaccine |
| Investigational medicinal product code | |
| Other name | Hexaxim ® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Arm title | Mexico (Group 5): MenACYW Conjugate Vaccine |
| Arm description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Arm title | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
| Arm description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0. | |
| Arm type | Active comparator |
| Investigational medicinal product name | DTaP-IPV-HB-Hib: Diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis, and Haemophilus influenzae type-b conjugate vaccine |
| Investigational medicinal product code | |
| Other name | Hexaxim ® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Arm title | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine |
| Arm description: Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0. | |
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: 0.5 mL, intramuscular, single dose on Day 0. | |
| Investigational medicinal product name | PCV13: Pneumococcal 13-valent Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | Prevenar 13 |
| Pharmaceutical forms | Suspension for injection |

| | |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

| | |
|------------------|---|
| Arm title | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|------------------|---|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW Conjugate vaccine: Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

| | |
|------------------|---|
| Arm title | Russian Federation (Group 9): PCV13 Vaccine |
|------------------|---|

Arm description:

Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 vaccine on Day 0.

| | |
|--|---|
| Arm type | Active comparator |
| Investigational medicinal product name | PCV13: Pneumococcal 13-valent Conjugate Vaccine |
| Investigational medicinal product code | |
| Other name | Prevenar 13 |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

0.5 mL, intramuscular, single dose on Day 0.

| Number of subjects in period 1 | South Korea(Group1): MenACYW Conjugate +MMR+ Varicella | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine |
|---------------------------------------|--|--|--|
| Started | 107 | 53 | 53 |
| Safety Analysis Set | 103 | 52 | 53 |
| Per-protocol Analysis Set | 92 ^[1] | 45 ^[2] | 50 ^[3] |
| Completed | 103 | 52 | 53 |
| Not completed | 4 | 1 | 0 |
| Consent withdrawn by subject | 4 | 1 | - |
| Adverse event, non-fatal | - | - | - |
| Lost to follow-up | - | - | - |
| Protocol deviation | - | - | - |

| Number of subjects in period 1 | Thailand (Group 10): MenACYW Conjugate | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine |
|---------------------------------------|--|--|--|
|---------------------------------------|--|--|--|

| | +MMR+Varicella Vaccine | | |
|------------------------------|------------------------|----|----|
| Started | 86 | 42 | 42 |
| Safety Analysis Set | 86 | 42 | 42 |
| Per-protocol Analysis Set | 85 ^[4] | 42 | 42 |
| Completed | 86 | 42 | 42 |
| Not completed | 0 | 0 | 0 |
| Consent withdrawn by subject | - | - | - |
| Adverse event, non-fatal | - | - | - |
| Lost to follow-up | - | - | - |
| Protocol deviation | - | - | - |

| Number of subjects in period 1 | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
|--------------------------------|--|--|--|
| Started | 200 | 100 | 100 |
| Safety Analysis Set | 200 | 100 | 100 |
| Per-protocol Analysis Set | 155 ^[5] | 79 ^[6] | 68 ^[7] |
| Completed | 190 | 97 | 95 |
| Not completed | 10 | 3 | 5 |
| Consent withdrawn by subject | 4 | - | 2 |
| Adverse event, non-fatal | - | 1 | - |
| Lost to follow-up | 5 | 2 | 3 |
| Protocol deviation | 1 | - | - |

| Number of subjects in period 1 | Russian Federation (Group 7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine |
|--------------------------------|--|--|--|
| Started | 200 | 100 | 100 |
| Safety Analysis Set | 200 | 100 | 99 |
| Per-protocol Analysis Set | 196 ^[8] | 96 ^[9] | 92 ^[10] |
| Completed | 200 | 100 | 99 |
| Not completed | 0 | 0 | 1 |
| Consent withdrawn by subject | - | - | 1 |
| Adverse event, non-fatal | - | - | - |
| Lost to follow-up | - | - | - |
| Protocol deviation | - | - | - |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study

vaccine, and had no protocol deviations.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Per-Protocol analysis set included all subjects who received at least 1 dose of study vaccine, and had no protocol deviations.

Baseline characteristics

Reporting groups

| | |
|---|--|
| Reporting group title | South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0. | |
| Reporting group title | South Korea (Group 2): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | South Korea (Group 3): MMR + Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0. | |
| Reporting group title | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0. | |
| Reporting group title | Thailand (Group 11): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Thailand (Group 12): MMR + Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0. | |
| Reporting group title | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0. | |
| Reporting group title | Mexico (Group 5): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0. | |
| Reporting group title | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0. | |
| Reporting group title | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Russian Federation (Group 9): PCV13 Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 | |

| Reporting group values | South Korea(Group1): MenACYW Conjugate +MMR+ Varicella | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine |
|------------------------------------|---|--|--|
| Number of subjects | 107 | 53 | 53 |
| Age categorical Units: Subjects | | | |

| | | | |
|--|----------------|----------------|----------------|
| Age continuous Units: months arithmetic mean standard deviation | 12.7 ± 1.58 | 12.7 ± 1.50 | 12.3 ± 0.96 |
| Gender categorical Units: Subjects | | | |
| Female | 49 | 18 | 29 |
| Male | 58 | 35 | 24 |
| Race Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 1 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 0 | 0 | 0 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 106 | 53 | 53 |
| Ethnicity Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 0 | 0 | 0 |
| Unknown or Not Reported | 107 | 53 | 53 |

| Reporting group values | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine |
|------------------------------------|---|--|--|
| Number of subjects | 86 | 42 | 42 |
| Age categorical Units: Subjects | | | |

| | | | |
|--|----------------|----------------|----------------|
| Age continuous Units: months arithmetic mean standard deviation | 12.4 ± 0.90 | 12.4 ± 0.88 | 12.8 ± 1.76 |
| Gender categorical Units: Subjects | | | |
| Female | 47 | 23 | 23 |
| Male | 39 | 19 | 19 |

| | | | |
|---|----|----|----|
| Race | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 86 | 42 | 42 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 0 | 0 | 0 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | 0 | 0 |
| Not Hispanic or Latino | 86 | 42 | 42 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|-------------------------------|--|---|---|
| Reporting group values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
| Number of subjects | 200 | 100 | 100 |
| Age categorical | | | |
| Units: Subjects | | | |

| | | | |
|---|--------|--------|--------|
| Age continuous | | | |
| Units: months | | | |
| arithmetic mean | 16.4 | 16.8 | 16.8 |
| standard deviation | ± 2.73 | ± 2.83 | ± 2.99 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 93 | 46 | 48 |
| Male | 107 | 54 | 52 |
| Race | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 0 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 200 | 100 | 99 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Ethnicity | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 200 | 100 | 98 |
| Not Hispanic or Latino | 0 | 0 | 2 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|-------------------------------|---|--|---|
| Reporting group values | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine |
| Number of subjects | 200 | 100 | 100 |

| | | | |
|--|----------------|----------------|----------------|
| Age categorical Units: Subjects | | | |
| Age continuous Units: months arithmetic mean standard deviation | 16.5 ± 2.36 | 16.0 ± 3.10 | 16.3 ± 2.26 |
| Gender categorical Units: Subjects | | | |
| Female | 78 | 51 | 45 |
| Male | 122 | 49 | 55 |
| Race Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Asian | 2 | 1 | 4 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 |
| White | 198 | 99 | 96 |
| More than one race | 0 | 0 | 0 |
| Unknown or Not Reported | 0 | 0 | 0 |
| Ethnicity Units: Subjects | | | |
| Hispanic or Latino | 4 | 0 | 1 |
| Not Hispanic or Latino | 196 | 100 | 99 |
| Unknown or Not Reported | 0 | 0 | 0 |

| | | | |
|------------------------------------|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 1183 | | |
| Age categorical Units: Subjects | | | |

| | | | |
|--|-----|--|--|
| Age continuous Units: months arithmetic mean standard deviation | - | | |
| Gender categorical Units: Subjects | | | |
| Female | 550 | | |
| Male | 633 | | |
| Race Units: Subjects | | | |
| American Indian or Alaska Native | 0 | | |
| Asian | 179 | | |
| Native Hawaiian or Other Pacific Islander | 0 | | |
| Black or African American | 0 | | |
| White | 792 | | |
| More than one race | 0 | | |
| Unknown or Not Reported | 212 | | |
| Ethnicity Units: Subjects | | | |

| | | | |
|-------------------------|-----|--|--|
| Hispanic or Latino | 403 | | |
| Not Hispanic or Latino | 567 | | |
| Unknown or Not Reported | 213 | | |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | South Korea(Group1): MenACYW Conjugate +MMR+ Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of Meningococcal Polysaccharide (Serogroups A, C, Y and W) Tetanus Toxoid (MenACYW) Conjugate vaccine, measles-mumps-rubella vaccine (MMR) vaccine, and varicella vaccine on Day 0. | |
| Reporting group title | South Korea (Group 2): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | South Korea (Group 3): MMR + Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0. | |
| Reporting group title | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine , MMR vaccine, and Varicella vaccine on Day 0. | |
| Reporting group title | Thailand (Group 11): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Thailand (Group 12): MMR + Varicella Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0. | |
| Reporting group title | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and diphtheria, tetanus, acellular pertussis, hepatitis B, poliomyelitis and Haemophilus influenzae type-b (DTaP-IPV-HB-Hib) vaccine on Day 0. | |
| Reporting group title | Mexico (Group 5): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0. | |
| Reporting group title | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate and pneumococcal Conjugate vaccine (PCV13) on Day 0. | |
| Reporting group title | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0. | |
| Reporting group title | Russian Federation (Group 9): PCV13 Vaccine |
| Reporting group description: Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 | |

vaccine on Day 0.

| | |
|----------------------------|--|
| Subject analysis set title | Groups 1 and 10: MenACYW Conjugate Vaccine + MMR + Varicella Vaccine |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

| | |
|----------------------------|--|
| Subject analysis set title | Groups 2 and 11: MenACYW Conjugate Vaccine |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW conjugate vaccine on Day 0.

| | |
|----------------------------|--|
| Subject analysis set title | Groups 3 and 12: MMR + Varicella Vaccine |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MMR vaccine and varicella vaccine on Day 0.

Primary: Geometric Mean Titers of MenACYW Antibodies Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

| | |
|-----------------|--|
| End point title | Geometric Mean Titers of MenACYW Antibodies Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11 ^{[1][2]} |
|-----------------|--|

End point description:

Antibody titers of MenACYW were measured by serum bactericidal assay using human complement (hSBA) assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS which included subjects who received at least one dose of the study vaccine(s), had a valid post-vaccination blood sample result and no protocol deviations. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

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

End point timeframe:

Day 0 and Day 30 post-vaccination

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: As the endpoint is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Russian Federation (Group 7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|--|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 79 | 196 | 96 |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serogroup A: Day 0 | 5.35 (4.82 to 5.94) | 5.49 (4.66 to 6.45) | 5.99 (5.30 to 6.76) | 8.54 (6.47 to 11.3) |
| Serogroup A: Day 30 | 31.4 (25.9 to 38.1) | 37.8 (28.5 to 50.2) | 24.6 (20.2 to 30.1) | 49.0 (36.8 to 65.3) |

| | | | | |
|---------------------|---------------------|---------------------|---------------------|---------------------|
| Serogroup C: Day 0 | 2.21 (2.11 to 2.31) | 2.16 (2.00 to 2.34) | 2.77 (2.43 to 3.16) | 3.69 (2.84 to 4.81) |
| Serogroup C: Day 30 | 749 (633 to 886) | 666 (538 to 825) | 205 (156 to 269) | 309 (218 to 437) |
| Serogroup Y: Day 0 | 2.63 (2.37 to 2.92) | 2.94 (2.45 to 3.53) | 2.90 (2.56 to 3.28) | 3.49 (2.68 to 4.53) |
| Serogroup Y: Day 30 | 79.7 (65.7 to 96.6) | 90.9 (66.8 to 124) | 139 (111 to 173) | 172 (130 to 229) |
| Serogroup W: Day 0 | 2.41 (2.22 to 2.62) | 2.16 (2.04 to 2.30) | 2.93 (2.54 to 3.38) | 3.62 (2.73 to 4.79) |
| Serogroup W: Day 30 | 40.0 (32.5 to 49.3) | 50.9 (37.2 to 69.8) | 57.4 (47.9 to 68.6) | 57.0 (44.3 to 73.5) |

| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine+MMR+Varicella Vaccine | Groups 2 and 11: MenACYW Conjugate Vaccine | | |
|--|--|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 177 | 87 | | |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serogroup A: Day 0 | 5.20 (4.56 to 5.93) | 6.10 (5.00 to 7.44) | | |
| Serogroup A: Day 30 | 43.9 (37.4 to 51.6) | 30.0 (23.1 to 39.0) | | |
| Serogroup C: Day 0 | 2.37 (2.11 to 2.65) | 2.58 (2.15 to 3.10) | | |
| Serogroup C: Day 30 | 876 (725 to 1057) | 600 (456 to 790) | | |
| Serogroup Y: Day 0 | 3.14 (2.78 to 3.54) | 3.12 (2.58 to 3.78) | | |
| Serogroup Y: Day 30 | 88.9 (75.1 to 105) | 60.0 (47.3 to 76.3) | | |
| Serogroup W: Day 0 | 2.15 (2.00 to 2.30) | 2.31 (2.02 to 2.64) | | |
| Serogroup W: Day 30 | 46.8 (39.1 to 56.0) | 35.5 (27.6 to 45.7) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Antibody Titers $\geq 1:4$ and $1:8$ Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Antibody Titers $\geq 1:4$ and $1:8$ Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11 ^{[3][4]} |
|-----------------|---|

End point description:

Antibody titers of Men A, C, Y, and W were measured by hSBA assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type Primary

End point timeframe:

Day 0 and Day 30 post-vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Russian Federation (Group 7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|------------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 79 | 196 | 96 |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A: Day 0 ($\geq 1:4$) | 82.6 (75.7 to 88.2) | 82.3 (72.1 to 90.0) | 82.1 (76.1 to 87.2) | 85.4 (76.7 to 91.8) |
| Serogroup A: Day 0 ($\geq 1:8$) | 45.8 (37.8 to 54.0) | 46.8 (35.5 to 58.4) | 49.0 (41.8 to 56.2) | 54.2 (43.7 to 64.4) |
| Serogroup A: Day 30 ($\geq 1:4$) | 98.1 (94.4 to 99.6) | 97.5 (91.2 to 99.7) | 94.9 (90.8 to 97.5) | 97.9 (92.7 to 99.7) |
| Serogroup A: Day 30 ($\geq 1:8$) | 92.9 (87.7 to 96.4) | 89.9 (81.0 to 95.5) | 83.7 (77.7 to 88.6) | 90.6 (82.9 to 95.6) |
| Serogroup C: Day 0 ($\geq 1:4$) | 12.3 (7.5 to 18.5) | 7.6 (2.8 to 15.8) | 19.9 (14.5 to 26.2) | 36.5 (26.9 to 46.9) |
| Serogroup C: Day 0 ($\geq 1:8$) | 1.9 (0.4 to 5.6) | 1.3 (0.0 to 6.9) | 8.7 (5.1 to 13.5) | 17.7 (10.7 to 26.8) |
| Serogroup C: Day 30 ($\geq 1:4$) | 100.0 (97.6 to 100.0) | 100.0 (95.4 to 100.0) | 98.5 (95.6 to 99.7) | 99.0 (94.3 to 100.0) |
| Serogroup C: Day 30 ($\geq 1:8$) | 100.0 (97.6 to 100.0) | 100.0 (95.4 to 100.0) | 93.9 (89.5 to 96.8) | 99.0 (94.3 to 100.0) |
| Serogroup Y: Day 0 ($\geq 1:4$) | 19.4 (13.5 to 26.5) | 25.3 (16.2 to 36.4) | 21.9 (16.4 to 28.4) | 32.3 (23.1 to 42.6) |
| Serogroup Y: Day 0 ($\geq 1:8$) | 11.0 (6.5 to 17.0) | 12.7 (6.2 to 22.0) | 14.3 (9.7 to 20.0) | 15.6 (9.0 to 24.5) |
| Serogroup Y: Day 30 ($\geq 1:4$) | 98.7 (95.4 to 99.8) | 100.0 (95.4 to 100.0) | 98.5 (95.6 to 99.7) | 99.0 (94.3 to 100.0) |
| Serogroup Y: Day 30 ($\geq 1:8$) | 98.7 (95.4 to 99.8) | 98.7 (93.1 to 100.0) | 97.4 (94.1 to 99.2) | 97.9 (92.7 to 99.7) |
| Serogroup W: Day 0 ($\geq 1:4$) | 14.8 (9.6 to 21.4) | 8.9 (3.6 to 17.4) | 16.8 (11.9 to 22.8) | 26.0 (17.6 to 36.0) |
| Serogroup W: Day 0 ($\geq 1:8$) | 7.7 (4.1 to 13.1) | 2.5 (0.3 to 8.8) | 12.8 (8.4 to 18.3) | 20.8 (13.2 to 30.3) |
| Serogroup W: Day 30 ($\geq 1:4$) | 97.4 (93.5 to 99.3) | 96.2 (89.3 to 99.2) | 95.9 (92.1 to 98.2) | 96.9 (91.1 to 99.4) |
| Serogroup W: Day 30 ($\geq 1:8$) | 90.3 (84.5 to 94.5) | 92.4 (84.2 to 97.2) | 94.4 (90.2 to 97.2) | 95.8 (89.7 to 98.9) |

| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine+MMR+Varicella Vaccine | Groups 2 and 11: MenACYW Conjugate Vaccine | | |
|------------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 177 | 87 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A: Day 0 ($\geq 1:4$) | 75.1 (68.1 to 81.3) | 82.8 (73.2 to 90.0) | | |
| Serogroup A: Day 0 ($\geq 1:8$) | 37.9 (30.7 to 45.4) | 44.8 (34.1 to 55.9) | | |
| Serogroup A: Day 30 ($\geq 1:4$) | 98.9 (96.0 to 99.9) | 95.4 (88.6 to 98.7) | | |
| Serogroup A: Day 30 ($\geq 1:8$) | 97.7 (94.3 to 99.4) | 92.0 (84.1 to 96.7) | | |
| Serogroup C: Day 0 ($\geq 1:4$) | 9.6 (5.7 to 14.9) | 16.1 (9.1 to 25.5) | | |
| Serogroup C: Day 0 ($\geq 1:8$) | 4.0 (1.6 to 8.0) | 6.9 (2.6 to 14.4) | | |
| Serogroup C: Day 30 ($\geq 1:4$) | 100.0 (97.9 to 100.0) | 100.0 (95.8 to 100.0) | | |
| Serogroup C: Day 30 ($\geq 1:8$) | 100.0 (97.9 to 100.0) | 100.0 (95.8 to 100.0) | | |
| Serogroup Y: Day 0 ($\geq 1:4$) | 32.2 (25.4 to 39.6) | 28.7 (19.5 to 39.4) | | |
| Serogroup Y: Day 0 ($\geq 1:8$) | 18.6 (13.2 to 25.2) | 17.2 (10.0 to 26.8) | | |
| Serogroup Y: Day 30 ($\geq 1:4$) | 99.4 (96.9 to 100.0) | 96.6 (90.3 to 99.3) | | |
| Serogroup Y: Day 30 ($\geq 1:8$) | 99.4 (96.9 to 100.0) | 95.4 (88.6 to 98.7) | | |
| Serogroup W: Day 0 ($\geq 1:4$) | 5.1 (2.4 to 9.4) | 11.5 (5.7 to 20.1) | | |
| Serogroup W: Day 0 ($\geq 1:8$) | 1.1 (0.1 to 4.0) | 2.3 (0.3 to 8.1) | | |
| Serogroup W: Day 30 ($\geq 1:4$) | 98.9 (96.0 to 99.9) | 96.6 (90.3 to 99.3) | | |
| Serogroup W: Day 30 ($\geq 1:8$) | 96.0 (92.0 to 98.4) | 92.0 (84.1 to 96.7) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With ≥ 4 -Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or With Other Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

| | |
|-----------------|--|
| End point title | Percentage of Subjects With ≥ 4 -Fold Rise in Antibody Titers Against Meningococcal Serogroups A, C, Y, and W Following |
|-----------------|--|

End point description:

Antibody titers of Meningococcal Serogroups A, C, Y, and W were measured by hSBA assay. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

End point type Primary

End point timeframe:

Day 0 up to Day 30 post-vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Russian Federation (Group 7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|----------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 79 | 196 | 96 |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A | 69.0 (61.1 to 76.2) | 70.9 (59.6 to 80.6) | 58.2 (50.9 to 65.2) | 72.9 (62.9 to 81.5) |
| Serogroup C | 100.0 (97.6 to 100.0) | 98.7 (93.1 to 100.0) | 92.3 (87.7 to 95.7) | 91.7 (84.2 to 96.3) |
| Serogroup Y | 96.8 (92.6 to 98.9) | 94.9 (87.5 to 98.6) | 94.4 (90.2 to 97.2) | 93.8 (86.9 to 97.7) |
| Serogroup W | 86.5 (80.0 to 91.4) | 92.4 (84.2 to 97.2) | 88.8 (83.5 to 92.8) | 90.6 (82.9 to 95.6) |

| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine+MMR+Varicella Vaccine | Groups 2 and 11: MenACYW Conjugate Vaccine | | |
|----------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 177 | 87 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A | 82.5 (76.1 to 87.8) | 64.4 (53.4 to 74.4) | | |
| Serogroup C | 98.3 (95.1 to 99.6) | 98.9 (93.8 to 100.0) | | |
| Serogroup Y | 95.5 (91.3 to 98.0) | 89.7 (81.3 to 95.2) | | |
| Serogroup W | 94.9 (90.6 to 97.6) | 89.7 (81.3 to 95.2) | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Vaccine Seroresponse for Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving hSBA Vaccine Seroresponse for Meningococcal Serogroups A, C, Y, and W Following Injection With MenACYW Conjugate Vaccine Administered Alone or Concomitantly With Paediatric Vaccines: Groups 1, 2, 4, 5, 7, 8, 10, and 11 ^{[7][8]} |
|-----------------|---|

End point description:

The hSBA vaccine seroresponse for serogroups A, C, Y, and W was defined as post-vaccination hSBA titers $\geq 1:16$ for subjects with pre-vaccination titers $< 1:8$ or at least a 4-fold increase in post-vaccination hSBA titers from pre- to post-vaccination, for subjects with pre-vaccination titers $\geq 1:8$. Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 2 and 11. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 3, 6, 9, and 12.

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

End point timeframe:

Day 30 post-vaccination

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Russian Federation (Group 7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|----------------------------------|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 155 | 79 | 196 | 96 |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A | 67.1 (59.1 to 74.4) | 69.6 (58.2 to 79.5) | 56.1 (48.9 to 63.2) | 71.9 (61.8 to 80.6) |
| Serogroup C | 100.0 (97.6 to 100) | 98.7 (93.1 to 100.0) | 90.8 (85.9 to 94.5) | 91.7 (84.2 to 96.3) |
| Serogroup Y | 92.3 (86.9 to 95.9) | 87.3 (78.0 to 93.8) | 92.9 (88.3 to 96.0) | 92.7 (85.6 to 97.0) |
| Serogroup W | 82.6 (75.7 to 88.2) | 82.3 (72.1 to 90.0) | 82.1 (76.1 to 87.2) | 90.6 (82.9 to 95.6) |

| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine+MMR+Varicella Vaccine | Groups 2 and 11: MenACYW Conjugate Vaccine | | |
|----------------------------------|--|--|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 177 | 87 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A | 78.5 (71.7 to 84.3) | 63.2 (52.2 to 73.3) | | |
| Serogroup C | 97.7 (94.3 to 99.4) | 98.9 (93.8 to 100.0) | | |
| Serogroup Y | 93.2 (88.5 to 96.4) | 88.5 (79.9 to 94.3) | | |
| Serogroup W | 86.4 (80.5 to 91.1) | 83.9 (74.5 to 90.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of MMR-Varicella Antibodies Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

| | |
|---|--|
| End point title | Geometric Mean Titers of MMR-Varicella Antibodies Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12 |
| End point description: | |
| Antibodies titers of Measles and Rubella were measured by enzyme immunoassay (EIA). Antibodies titers for mumps and varicella were measured by enzyme-linked immunosorbent assay (ELISA). Data for this endpoint was reported for the combined population of Groups 1 and 10, Groups 3 and 12. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 2, 4, 5, 6, 7, 8, 9, and 11. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 0 and Day 30 post-vaccination | |

| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine+MMR+Varicella Vaccine | Groups 3 and 12: MMR + Varicella Vaccine | | |
|------------------|--|--|--|--|
|------------------|--|--|--|--|

| Subject group type | Subject analysis set | Subject analysis set | | |
|--|------------------------|------------------------|--|--|
| Number of subjects analysed | 177 | 92 | | |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Measles: Day 0 (n=176,92) | 40.0 (37.2 to 43.1) | 45.0 (40.1 to 50.4) | | |
| Measles: Day 30 (n=177,92) | 2156 (1893 to 2455) | 2840 (2389 to 3378) | | |
| Mumps: Day 0 (n=176,92) | 5.51 (5.20 to 5.84) | 5.43 (5.05 to 5.83) | | |
| Mumps: Day 30 (n=177,92) | 85.9 (74.7 to 98.7) | 97.6 (83.1 to 115) | | |
| Rubella: Day 0 (n=176,92) | 5.94 (5.32 to 6.63) | 7.12 (6.07 to 8.34) | | |
| Rubella: Day 30 (n=177,92) | 87.6 (79.4 to 96.7) | 104 (91.2 to 118) | | |
| Varicella: Day 0 (n=176,92) | 0.556 (0.484 to 0.638) | 0.665 (0.508 to 0.869) | | |
| Varicella: Day 30 (n=177,92) | 13.4 (11.6 to 15.4) | 17.4 (15.2 to 19.9) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12

| | |
|-----------------|--|
| End point title | Percentage of Subjects With Immune Response Following Injection With MMR-Varicella Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 1, 3, 10, and 12 |
|-----------------|--|

End point description:

Immune response for MMR-Varicella vaccine was defined as: anti-measles Antibody (Ab) concentrations ≥ 255 milli-international unit per milliliter (mIU/mL), anti-mumps Ab concentrations ≥ 10 Ab units/mL, anti-rubella Ab concentrations ≥ 10 international unit per milliliter (IU/mL), anti-varicella Ab concentrations ≥ 5 glycoprotein enzyme-linked immunosorbent assay (gpELISA) Ab units/mL. Data for this endpoint was planned to be analysed and reported for the combined population of Groups 1 and 10, Groups 3 and 12. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 2, 4, 5, 6, 7, 8, 9, and 11.

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

End point timeframe:

Day 0 and Day 30 post-vaccination

| | | | | |
|-------------------------|--|--|--|--|
| End point values | Groups 1 and 10: MenACYW Conjugate Vaccine + MMR + Varicella Vaccine | Groups 3 and 12: MMR + Varicella Vaccine | | |
|-------------------------|--|--|--|--|

| | | | | |
|----------------------------------|----------------------|-----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 177 | 92 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Measles: Day 0 (n=176,92) | 0.6 (0.0 to 3.1) | 0.0 (0.0 to 3.9) | | |
| Measles: Day 30 (n=177,92) | 96.6 (92.8 to 98.7) | 97.8 (92.4 to 99.7) | | |
| Mumps: Day 0 (n=176,92) | 7.4 (4.0 to 12.3) | 6.5 (2.4 to 13.7) | | |
| Mumps: Day 30 (n=177,92) | 97.7 (94.3 to 99.4) | 100.0 (96.1 to 100.0) | | |
| Rubella: Day 0 (n=176,92) | 27.3 (20.8 to 34.5) | 31.5 (22.2 to 42.0) | | |
| Rubella: Day 30 (n=177,92) | 100.0 (97.9 to 100) | 100.0 (96.1 to 100) | | |
| Varicella: Day 0 (n=176,92) | 4.0 (1.6 to 8.0) | 7.6 (3.1 to 15.1) | | |
| Varicella: Day 30 (n=177,92) | 93.2 (88.5 to 96.4) | 98.9 (94.1 to 100.0) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

| | |
|-----------------|--|
| End point title | Geometric Mean Titers of Pertussis Toxoid (PT) and Filamentous Hemagglutinin (FHA) Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6 ^[9] |
|-----------------|--|

End point description:

Antibodies titers of PT and FHA were measured by electrochemiluminescent (ECL) assay. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

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

End point timeframe:

Day 0 and Day 30 post-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: This endpoint was evaluated for reported arms only.

| | | | | |
|--|---|---|--|--|
| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 | 68 | | |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|-------------|---------------------|---------------------|--|--|
| PT: Day 0 | 17.9 (15.1 to 21.3) | 20.4 (15.3 to 27.0) | | |
| PT: Day 30 | 144 (130 to 159) | 169 (144 to 198) | | |
| FHA: Day 0 | 45.5 (37.0 to 55.9) | 57.4 (41.4 to 79.5) | | |
| FHA: Day 30 | 299 (265 to 337) | 391 (319 to 480) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of DTaP-IPV-HB-Hib Antibodies Following Injection With DTaP-IPV-HB-Hib Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 4 and 6

| | |
|-----------------|---|
| End point title | Geometric Mean Titers of DTaP-IPV-HB-Hib Antibodies Following Injection With DTaP-IPV-HB-Hib Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 4 and 6 ^[10] |
|-----------------|---|

End point description:

Antibodies titers of Diphtheria, Tetanus and Pertussis were measured by ECL assay. Antibodies titers of poliovirus types 1, 2, and 3 were measured by neutralization assay. Antibodies titers of Hepatitis B were measured by an immunodiagnostic system using chemiluminescence detection. Antibodies titers of Polyribosyl-ribitol phosphate (PRP) were measured by Farr-type radioimmunoassay (RIA). Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

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

End point timeframe:

Day 0 (for tetanus only) and Day 30 post-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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | | |
|--|---|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 | 68 | | |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Diphtheria: Day 30 (n =155,68) | 5.52 (4.94 to 6.17) | 6.34 (5.51 to 7.30) | | |
| Tetanus: Day 0 (n =155, 67) | 0.238 (0.196 to 0.289) | 0.234 (0.177 to 0.309) | | |
| Tetanus: Day 30 (n =155,68) | 7.06 (6.01 to 8.29) | 7.11 (5.79 to 8.74) | | |
| Polio 1: Day 30 (n=155,68) | 4560 (3870 to 5373) | 4034 (3052 to 5332) | | |
| Polio 2: Day 30 (n=155,68) | 7244 (6208 to 8453) | 5618 (4578 to 6895) | | |

| | | | | |
|--------------------------------|---------------------|----------------------|--|--|
| Polio 3: Day 30 (n=155,68) | 5977 (4958 to 7205) | 5100 (3840 to 6772) | | |
| Hepatitis B: Day 30 (n=155,68) | 5171 (4104 to 6515) | 7308 (5135 to 10401) | | |
| PRP: Day30 (n=155,68) | 46.6 (39.6 to 54.9) | 56.2 (41.5 to 76.1) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Immune Response Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6 ^[11] |
|-----------------|---|

End point description:

Immune response for DTaP-IPV-HB-Hib vaccine was defined as: anti-tetanus Ab concentrations: ≥ 0.01 and 0.1 IU/mL at Day 0 and ≥ 0.1 and 1.0 IU/mL at Day 30, anti-diphtheria Ab concentrations: ≥ 0.1 and 1.0 IU/mL, anti-PRP Ab concentrations and ≥ 0.15 and 1.0 microgram per milliliter (mcg/mL), anti-poliovirus types 1, 2, and 3 Ab titers $\geq 1:8$, anti-hepatitis B surface antigen Ab concentrations ≥ 10 mIU/mL, ≥ 100 mIU/mL. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11 and 12.

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

End point timeframe:

Day 0 (tetanus only) and Day 30 post-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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | | |
|--|---|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 | 68 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Diphtheria: Day 30 (≥ 0.1 IU/mL)(n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Diphtheria: Day 30 (≥ 1 IU/mL) (n=155,68) | 98.7 (95.4 to 99.8) | 100.0 (94.7 to 100) | | |
| Tetanus: Day 0 (≥ 0.01 IU/mL) (n=155,67) | 100.0 (97.6 to 100) | 100.0 (94.6 to 100) | | |
| Tetanus: Day 0 (≥ 0.1 IU/mL) (n=155,67) | 81.3 (74.2 to 87.1) | 77.6 (65.8 to 86.9) | | |
| Tetanus: Day 30 (≥ 0.1 IU/mL) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Tetanus: Day 30 (≥ 1 IU/mL) (n=155,68) | 98.1 (94.4 to 99.6) | 98.5 (92.1 to 100.0) | | |

| | | | | |
|--|---------------------|---------------------|--|--|
| Polio 1: Day 30 (≥ 8 [1/dilution]) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Polio 2: Day 30 (≥ 8 [1/dilution]) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Polio 3: Day 30 (≥ 8 [1/dilution]) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Hepatitis B: Day 30 (≥ 10 mIU/mL) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| Hepatitis B: Day 30 (≥ 100 mIU/mL) (n=155,68) | 98.7 (95.4 to 99.8) | 100.0 (94.7 to 100) | | |
| PRP: Day 30 (≥ 0.15 mcg/mL) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |
| PRP: Day 30 (≥ 1.0 mcg/mL) (n=155,68) | 100.0 (97.6 to 100) | 100.0 (94.7 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Vaccine Response of PT and FHA Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Vaccine Response of PT and FHA Antibodies Following Injection With DTaP-IPV-HB-Hib Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 4 and 6 ^[12] |
|-----------------|---|

End point description:

Pertussis and FHA vaccine response was defined as: if the pre-vaccination concentration is $< 4 \times$ lower limit of quantification (LLOQ is equal to 2), then the post-vaccination concentration is $\geq 4 \times$ pre-vaccination concentration and if the pre-vaccination concentration is $\geq 4 \times$ LLOQ, then the post-vaccination concentration is $\geq 2 \times$ pre-vaccination concentration. Analysis was performed on PPAS. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 5, 7, 8, 9, 10, 11, and 12.

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

End point timeframe:

Day 0 and Day 30 post-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: This endpoint was evaluated for reported arms only.

| | | | | |
|----------------------------------|---|---|--|--|
| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 155 | 68 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| PT: Day 30/Day 0 | 91.0 (85.3 to 95.0) | 92.6 (83.7 to 97.6) | | |
| FHA: Day 30/Day 0 | 89.0 (83.0 to 93.5) | 88.2 (78.1 to 94.8) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of PCV13 Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F Antibodies Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 7 and 9

| | |
|-----------------|--|
| End point title | Geometric Mean Titers of PCV13 Serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F Antibodies Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With the MenACYW Conjugate Vaccine: Groups 7 and 9 ^[13] |
|-----------------|--|

End point description:

Antibodies of pneumococcal serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F were measured by ECL assay. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 4, 5, 6, 8, 10, 11, and 12.

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

End point timeframe:

Day 0 and Day 30 post-vaccination

Notes:

[13] - 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: This endpoint was evaluated for reported arms only.

| End point values | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 9): PCV13 Vaccine | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 196 | 92 | | |
| Units: titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: Day 0 (n=193,92) | 0.867 (0.741 to 1.01) | 0.918 (0.713 to 1.18) | | |
| Serotype 1: Day 30 (n=191,92) | 2.33 (1.98 to 2.75) | 2.14 (1.63 to 2.81) | | |
| Serotype 3: Day 0 (n=193,92) | 0.409 (0.341 to 0.491) | 0.414 (0.322 to 0.533) | | |
| Serotype 3: Day 30 (n=191,92) | 0.802 (0.664 to 0.967) | 0.773 (0.608 to 0.983) | | |
| Serotype 4: Day 0 (n=193,92) | 0.604 (0.511 to 0.715) | 0.653 (0.507 to 0.840) | | |
| Serotype 4: Day 30 (n=191,92) | 1.97 (1.68 to 2.31) | 1.49 (1.15 to 1.93) | | |
| Serotype 5: Day 0 (n=193,92) | 0.828 (0.719 to 0.953) | 0.782 (0.610 to 1.00) | | |

| | | | | |
|---------------------------------|------------------------|------------------------|--|--|
| Serotype 5: Day 30 (n=191,92) | 1.99 (1.70 to 2.31) | 1.73 (1.33 to 2.24) | | |
| Serotype 6A: Day 0 (n=193,92) | 1.61 (1.33 to 1.95) | 1.48 (1.09 to 2.00) | | |
| Serotype 6A: Day 30 (n=191,92) | 5.96 (4.99 to 7.13) | 6.13 (4.47 to 8.41) | | |
| Serotype 6B: Day 0 (n=193,92) | 0.895 (0.715 to 1.12) | 0.691 (0.514 to 0.929) | | |
| Serotype 6B: Day 30 (n=191,92) | 3.66 (2.99 to 4.50) | 2.57 (1.83 to 3.61) | | |
| Serotype 7F: Day 0 (n=193,92) | 1.32 (1.12 to 1.55) | 1.39 (1.08 to 1.77) | | |
| Serotype 7F: Day 30 (n=191,92) | 3.05 (2.59 to 3.58) | 2.67 (2.05 to 3.47) | | |
| Serotype 9V: Day 0 (n=193,92) | 0.841 (0.710 to 0.997) | 0.863 (0.660 to 1.13) | | |
| Serotype 9V: Day 30 (n=191,92) | 2.34 (1.95 to 2.81) | 2.52 (1.92 to 3.30) | | |
| Serotype 14: Day 0 (n=192,92) | 3.25 (2.74 to 3.86) | 3.00 (2.30 to 3.91) | | |
| Serotype 14: Day 30 (n=191,92) | 7.62 (6.56 to 8.83) | 6.30 (5.00 to 7.93) | | |
| Serotype 18C: Day 0 (n=193,92) | 0.737 (0.620 to 0.876) | 0.995 (0.766 to 1.29) | | |
| Serotype 18C: Day 30 (n=191,92) | 2.19 (1.87 to 2.58) | 2.21 (1.73 to 2.83) | | |
| Serotype 19A: Day 0 (n=193,92) | 1.65 (1.36 to 2.01) | 1.96 (1.46 to 2.64) | | |
| Serotype 19A: Day 30 (n=191,92) | 5.75 (4.85 to 6.80) | 5.91 (4.54 to 7.69) | | |
| Serotype 19F: Day 0 (n=193,92) | 1.78 (1.43 to 2.21) | 1.74 (1.28 to 2.35) | | |
| Serotype 19F: Day 30 (n=191,92) | 5.58 (4.57 to 6.81) | 5.53 (3.98 to 7.69) | | |
| Serotype 23F: Day 0 (n=192,92) | 0.631 (0.519 to 0.768) | 0.733 (0.537 to 1.00) | | |
| Serotype 23F: Day 30 (n=191,92) | 2.42 (2.04 to 2.86) | 2.58 (1.98 to 3.37) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Immune Response Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 7 and 9

| | |
|------------------------|---|
| End point title | Percentage of Subjects With Immune Response Following Injection With PCV13 Vaccine Administered Alone or Concomitantly With The MenACYW Conjugate Vaccine: Groups 7 and 9 ^[14] |
| End point description: | Immune response for PCV13 for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F was defined as antibodies concentrations ≥ 0.35 mcg/mL or ≥ 1.0 mcg/mL. Analysis was performed on PPAS. Here, 'n' = subjects with available data for each specified category. Data for this endpoint were not planned to be collected and analysed for Groups 1, 2, 3, 4, 5, 6, 8, 10, 11, and 12. |
| End point type | Secondary |
| End point timeframe: | Day 0 and Day 30 post-vaccination |

Notes:

[14] - 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: This endpoint was evaluated for reported arms only.

| End point values | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 9): PCV13 Vaccine | | |
|--|--|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 196 | 92 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1: Day 0 (≥ 0.35 mcg/mL)(n=193,92) | 80.8 (74.6 to 86.1) | 79.3 (69.6 to 87.1) | | |
| Serotype 1: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 43.0 (35.9 to 50.3) | 45.7 (35.2 to 56.4) | | |
| Serotype 1: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 97.4 (94.0 to 99.1) | 94.6 (87.8 to 98.2) | | |
| Serotype 1: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 76.4 (69.8 to 82.3) | 70.7 (60.2 to 79.7) | | |
| Serotype 3: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 49.2 (42.0 to 56.5) | 53.3 (42.6 to 63.7) | | |
| Serotype 3: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 22.3 (16.6 to 28.8) | 18.5 (11.1 to 27.9) | | |
| Serotype 3: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 72.3 (65.3 to 78.5) | 76.1 (66.1 to 84.4) | | |
| Serotype 3: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 48.2 (40.9 to 55.5) | 38.0 (28.1 to 48.8) | | |
| Serotype 4: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 66.8 (59.7 to 73.4) | 68.5 (58.0 to 77.8) | | |
| Serotype 4: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 33.7 (27.1 to 40.8) | 38.0 (28.1 to 48.8) | | |
| Serotype 4: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 92.7 (88.0 to 95.9) | 90.2 (82.2 to 95.4) | | |
| Serotype 4: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 80.1 (73.7 to 85.5) | 62.0 (51.2 to 71.9) | | |
| Serotype 5: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 81.3 (75.1 to 86.6) | 76.1 (66.1 to 84.4) | | |
| Serotype 5: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 41.5 (34.4 to 48.7) | 50.0 (39.4 to 60.6) | | |
| Serotype 5: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 94.8 (90.6 to 97.5) | 90.2 (82.2 to 95.4) | | |
| Serotype 5: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 71.2 (64.2 to 77.5) | 69.6 (59.1 to 78.7) | | |
| Serotype 6A: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 90.2 (85.1 to 94.0) | 82.6 (73.3 to 89.7) | | |
| Serotype 6A: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 63.7 (56.5 to 70.5) | 65.2 (54.6 to 74.9) | | |
| Serotype 6A: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 97.4 (94.0 to 99.1) | 96.7 (90.8 to 99.3) | | |
| Serotype 6A: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 96.3 (92.6 to 98.5) | 90.2 (82.2 to 95.4) | | |
| Serotype 6B: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 72.0 (65.1 to 78.2) | 68.5 (58.0 to 77.8) | | |
| Serotype 6B: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 44.6 (37.4 to 51.9) | 41.3 (31.1 to 52.1) | | |

| | | | | |
|--|---------------------|----------------------|--|--|
| Serotype 6B: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 94.8 (90.6 to 97.5) | 92.4 (84.9 to 96.9) | | |
| Serotype 6B: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 86.4 (80.7 to 90.9) | 75.0 (64.9 to 83.4) | | |
| Serotype 7F: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 87.0 (81.5 to 91.4) | 88.0 (79.6 to 93.9) | | |
| Serotype 7F: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 62.7 (55.5 to 69.5) | 65.2 (54.6 to 74.9) | | |
| Serotype 7F: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 98.4 (95.5 to 99.7) | 94.6 (87.8 to 98.2) | | |
| Serotype 7F: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 80.1 (73.7 to 85.5) | 83.7 (74.5 to 90.6) | | |
| Serotype 9V: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 77.2 (70.6 to 82.9) | 79.3 (69.6 to 87.1) | | |
| Serotype 9V: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 42.0 (34.9 to 49.3) | 43.5 (33.2 to 54.2) | | |
| Serotype 9V: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 95.3 (91.2 to 97.8) | 92.4 (84.9 to 96.9) | | |
| Serotype 9V: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 74.3 (67.5 to 80.4) | 75.0 (64.9 to 83.4) | | |
| Serotype 14: Day 0 (≥ 0.35 mcg/mL) (n=192,92) | 95.8 (92.0 to 98.2) | 92.4 (84.9 to 96.9) | | |
| Serotype 14: Day 0 (≥ 1.0 mcg/mL) (n=192,92) | 83.3 (77.3 to 88.3) | 87.0 (78.0 to 93.1) | | |
| Serotype 14: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 99.0 (96.3 to 99.9) | 98.9 (94.1 to 100.0) | | |
| Serotype 14: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 97.4 (94.0 to 99.1) | 94.6 (87.8 to 98.2) | | |
| Serotype 18C: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 71.5 (64.6 to 77.8) | 84.8 (75.8 to 91.4) | | |
| Serotype 18C: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 40.9 (33.9 to 48.2) | 48.9 (38.3 to 59.6) | | |
| Serotype 18C: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 95.3 (91.2 to 97.8) | 92.4 (84.9 to 96.9) | | |
| Serotype 18C: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 79.1 (72.6 to 84.6) | 79.3 (69.6 to 87.1) | | |
| Serotype 19A: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 87.0 (81.5 to 91.4) | 87.0 (78.3 to 93.1) | | |
| Serotype 19A: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 62.7 (55.5 to 69.5) | 69.6 (59.1 to 78.7) | | |
| Serotype 19A: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 96.3 (92.6 to 98.5) | 98.9 (94.1 to 100.0) | | |
| Serotype 19A: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 92.7 (88.0 to 95.9) | 90.2 (82.2 to 95.4) | | |
| Serotype 19F: Day 0 (≥ 0.35 mcg/mL) (n=193,92) | 87.0 (81.5 to 91.4) | 89.1 (80.9 to 94.7) | | |
| Serotype 19F: Day 0 (≥ 1.0 mcg/mL) (n=193,92) | 64.2 (57.0 to 71.0) | 65.2 (54.6 to 74.9) | | |
| Serotype 19F: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 96.9 (93.3 to 98.8) | 97.8 (92.4 to 99.7) | | |
| Serotype 19F: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 88.0 (82.5 to 92.2) | 85.9 (77.0 to 92.3) | | |
| Serotype 23F: Day 0 (≥ 0.35 mcg/mL) (n=192,92) | 68.2 (61.1 to 74.7) | 64.1 (53.5 to 73.9) | | |
| Serotype 23F: Day 0 (≥ 1.0 mcg/mL) (n=192,92) | 34.9 (28.2 to 42.1) | 44.6 (34.2 to 55.3) | | |
| Serotype 23F: Day 30 (≥ 0.35 mcg/mL) (n=191,92) | 96.3 (92.6 to 98.5) | 93.5 (86.3 to 97.6) | | |
| Serotype 23F: Day 30 (≥ 1.0 mcg/mL) (n=191,92) | 72.3 (65.3 to 78.5) | 78.3 (68.4 to 86.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 1, 2, 3, 10, 11 and 12

| | |
|-----------------|--|
| End point title | Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 1, 2, 3, 10, 11 and 12 ^[15] |
|-----------------|--|

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: ≥ 50 millimeter (mm). Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on safety analysis set which included all subjects who received at least 1 dose of study vaccine and had any safety data available. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

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

End point timeframe:

Within 7 days post vaccination

Notes:

[15] - 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: Data for Groups 4, 5, 6, 7, 8, and 9 are reported in separate endpoints.

| End point values | South Korea(Group1) : MenACYW Conjugate +MMR+ Varicella Vaccine | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella a Vaccine |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 103 | 52 | 53 | 86 |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| MenACYW: Tenderness: Any Grade | 28 | 15 | 99999 | 25 |
| MenACYW: Tenderness: Grade 3 | 1 | 0 | 99999 | 0 |
| MenACYW: Erythema: Any Grade | 27 | 20 | 99999 | 21 |
| MenACYW: Erythema: Grade 3 | 0 | 2 | 99999 | 0 |
| MenACYW: Swelling: Any Grade | 18 | 14 | 99999 | 13 |
| MenACYW: Swelling: Grade 3 | 0 | 0 | 99999 | 0 |
| MMR: Tenderness: Any Grade | 21 | 99999 | 10 | 17 |
| MMR: Tenderness: Grade 3 | 1 | 99999 | 0 | 0 |
| MMR: Erythema: Any Grade | 13 | 99999 | 6 | 17 |
| MMR: Erythema: Grade 3 | 0 | 99999 | 0 | 0 |
| MMR: Swelling: Any Grade | 7 | 99999 | 1 | 11 |
| MMR: Swelling: Grade 3 | 0 | 99999 | 0 | 0 |
| Varicella: Tenderness: Any Grade | 23 | 99999 | 11 | 15 |
| Varicella: Tenderness: Grade 3 | 0 | 99999 | 0 | 0 |

| | | | | |
|--------------------------------|----|-------|---|----|
| Varicella: Erythema: Any Grade | 19 | 99999 | 4 | 13 |
| Varicella: Erythema: Grade 3 | 1 | 99999 | 0 | 0 |
| Varicella: Swelling: Any Grade | 10 | 99999 | 2 | 11 |
| Varicella: Swelling: Grade 3 | 0 | 99999 | 0 | 0 |

| End point values | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine | | |
|----------------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 42 | 42 | | |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| MenACYW: Tenderness: Any Grade | 15 | 99999 | | |
| MenACYW: Tenderness: Grade 3 | 1 | 99999 | | |
| MenACYW: Erythema: Any Grade | 6 | 99999 | | |
| MenACYW: Erythema: Grade 3 | 0 | 99999 | | |
| MenACYW: Swelling: Any Grade | 5 | 99999 | | |
| MenACYW: Swelling: Grade 3 | 0 | 99999 | | |
| MMR: Tenderness: Any Grade | 99999 | 17 | | |
| MMR: Tenderness: Grade 3 | 99999 | 0 | | |
| MMR: Erythema: Any Grade | 99999 | 6 | | |
| MMR: Erythema: Grade 3 | 99999 | 0 | | |
| MMR: Swelling: Any Grade | 99999 | 3 | | |
| MMR: Swelling: Grade 3 | 99999 | 0 | | |
| Varicella: Tenderness: Any Grade | 99999 | 13 | | |
| Varicella: Tenderness: Grade 3 | 99999 | 1 | | |
| Varicella: Erythema: Any Grade | 99999 | 6 | | |
| Varicella: Erythema: Grade 3 | 99999 | 0 | | |
| Varicella: Swelling: Any Grade | 99999 | 4 | | |
| Varicella: Swelling: Grade 3 | 99999 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 4, 5 and 6

| | |
|-----------------|--|
| End point title | Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 4, 5 and 6 ^[16] |
|-----------------|--|

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: ≥ 50 mm. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on safety analysis set. Here, 'n' = subjects with available data for each specified category. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

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

End point timeframe:

Within 7 days post vaccination

Notes:

[16] - 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: This endpoint was evaluated for reported arms only.

| End point values | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | |
|--|---|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 200 | 100 | 100 | |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| MenACYW: Tenderness: Any Grade(n=191,98,100) | 68 | 27 | 99999 | |
| MenACYW: Tenderness: Grade 3 (n=191,98,100) | 6 | 1 | 99999 | |
| MenACYW: Erythema: Any Grade (n=191,98,100) | 40 | 15 | 99999 | |
| MenACYW: Erythema: Grade 3 (n=191,98,100) | 3 | 3 | 99999 | |
| MenACYW: Swelling: Any Grade (n=191,98,100) | 23 | 8 | 99999 | |
| MenACYW: Swelling: Grade 3 (n=191,98,100) | 2 | 2 | 99999 | |
| DTaP-IPV-HB-Hib:Tenderness:Any Grade(n=191,100,95) | 80 | 99999 | 54 | |
| DTaP-IPV-HB-Hib: Tenderness:Grade 3 (n=191,100,95) | 6 | 99999 | 10 | |
| DTaP-IPV-HB-Hib: Erythema:Any Grade (n=191,100,95) | 56 | 99999 | 37 | |
| DTaP-IPV-HB-Hib: Erythema: Grade 3 (n=191,100,95) | 8 | 99999 | 5 | |
| DTaP-IPV-HB-Hib: Swelling:Any Grade (n=191,100,95) | 45 | 99999 | 30 | |
| DTaP-IPV-HB-Hib: Swelling: Grade 3 (n=191,100,95) | 8 | 99999 | 4 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 7, 8 and 9

| | |
|-----------------|--|
| End point title | Number of Subjects Reporting at Least One Solicited Injection Site Reactions (Tenderness, Erythema, Swelling): Groups 7, 8 and 9 ^[17] |
|-----------------|--|

End point description:

Solicited injection site reactions: tenderness, erythema and swelling. Tenderness: Grade 3: cries when injected limb moved, or the movement of the injected limb reduced, Erythema and swelling: Grade 3: >= 50 mm. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on Safety analysis set. Here, '99999' was used as space fillers and indicate that vaccine was not administered to the specified group.

| | |
|---------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Within 07 days post vaccination | |

Notes:

[17] - 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: Data for Groups 1, 2, 3, 10, 11, 12, 4, 5, and 6 are reported in separate endpoints.

| End point values | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine | |
|--------------------------------|--|---|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 200 | 100 | 99 | |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| MenACYW: Tenderness: Any Grade | 28 | 8 | 99999 | |
| MenACYW: Tenderness: Grade 3 | 4 | 0 | 99999 | |
| MenACYW: Erythema: Any Grade | 43 | 17 | 99999 | |
| MenACYW: Erythema: Grade 3 | 0 | 0 | 99999 | |
| MenACYW: Swelling: Any Grade | 8 | 7 | 99999 | |
| MenACYW: Swelling: Grade 3 | 0 | 0 | 99999 | |
| PCV13: Tenderness: Any Grade | 34 | 99999 | 9 | |
| PCV13: Tenderness: Grade 3 | 5 | 99999 | 1 | |
| PCV13: Erythema: Any Grade | 48 | 99999 | 8 | |
| PCV13: Erythema: Grade 3 | 0 | 99999 | 0 | |
| PCV13: Swelling: Any Grade | 19 | 99999 | 2 | |
| PCV13: Swelling: Grade 3 | 0 | 99999 | 0 | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects Reporting at Least One Solicited Systemic Reactions (Fever, Vomiting, Abnormal Crying, Drowsiness, Appetite Loss, Irritability)

| | |
|-----------------|--|
| End point title | Number of Subjects Reporting at Least One Solicited Systemic Reactions (Fever, Vomiting, Abnormal Crying, Drowsiness, Appetite Loss, Irritability) |
|-----------------|--|

End point description:

Solicited systemic reaction: Fever: Grade 3: > 39.5°C, Vomiting: Grade 3: >= 6 episodes per 24 hours or requiring parenteral hydration, Crying abnormal: Grade 3: >3 hours, Drowsiness: Grade 3: sleeping most of the time or difficult to wake up, Appetite lost: Grade 3: refuses >= 3 feeds/meals or refuses most feeds/meals, Irritability: Grade 3: inconsolable. Percentage of subjects with any of the Grade and Grade 3 solicited injection-site reactions were reported. Analysis was performed on Safety analysis set. Here, 'number of subjects analysed' = subjects evaluable for this endpoint.

| | |
|---------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Within 07 days post vaccination | |

| End point values | South Korea(Group1) : MenACYW Conjugate +MMR+ Varicella Vaccine | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine | Thailand (Group 10): MenACYW Conjugate +MMR+Varicella Vaccine |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 103 | 52 | 53 | 86 |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| Fever: Any Grade | 17 | 9 | 5 | 6 |
| Fever: Grade 3 | 1 | 2 | 1 | 0 |
| Vomiting: Any Grade | 6 | 3 | 2 | 5 |
| Vomiting: Grade 3 | 0 | 0 | 0 | 0 |
| Abnormal crying: Any Grade | 21 | 9 | 6 | 14 |
| Abnormal crying: Grade 3 | 0 | 0 | 0 | 0 |
| Drowsiness: Any Grade | 17 | 8 | 9 | 8 |
| Drowsiness: Grade 3 | 0 | 0 | 0 | 0 |
| Appetite Lost: Any Grade | 29 | 10 | 8 | 11 |
| Appetite Lost: Grade 3 | 1 | 0 | 0 | 0 |
| Irritability: Any Grade | 31 | 12 | 11 | 14 |
| Irritability: Grade 3 | 0 | 0 | 0 | 0 |

| End point values | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB- Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine |
|-----------------------------|--|--|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 42 | 42 | 191 | 98 |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| Fever: Any Grade | 1 | 3 | 32 | 7 |
| Fever: Grade 3 | 1 | 0 | 4 | 1 |
| Vomiting: Any Grade | 4 | 5 | 15 | 6 |
| Vomiting: Grade 3 | 0 | 1 | 0 | 1 |
| Abnormal crying: Any Grade | 14 | 12 | 46 | 25 |
| Abnormal crying: Grade 3 | 0 | 0 | 1 | 1 |
| Drowsiness: Any Grade | 7 | 7 | 31 | 15 |
| Drowsiness: Grade 3 | 0 | 1 | 1 | 0 |
| Appetite Lost: Any Grade | 12 | 5 | 51 | 25 |
| Appetite Lost: Grade 3 | 0 | 2 | 8 | 2 |
| Irritability: Any Grade | 11 | 14 | 64 | 34 |
| Irritability: Grade 3 | 1 | 0 | 4 | 1 |

| End point values | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine |
|-----------------------------|---|--|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 95 | 200 | 100 | 99 |
| Units: subjects | | | | |
| number (not applicable) | | | | |
| Fever: Any Grade | 16 | 12 | 3 | 2 |
| Fever: Grade 3 | 0 | 0 | 0 | 0 |
| Vomiting: Any Grade | 9 | 0 | 0 | 0 |
| Vomiting: Grade 3 | 0 | 0 | 0 | 0 |
| Abnormal crying: Any Grade | 26 | 8 | 4 | 2 |
| Abnormal crying: Grade 3 | 1 | 2 | 0 | 0 |
| Drowsiness: Any Grade | 17 | 25 | 6 | 4 |
| Drowsiness: Grade 3 | 2 | 1 | 0 | 0 |
| Appetite Lost: Any Grade | 20 | 19 | 12 | 7 |
| Appetite Lost: Grade 3 | 3 | 1 | 0 | 0 |
| Irritability: Any Grade | 33 | 26 | 16 | 9 |
| Irritability: Grade 3 | 3 | 4 | 0 | 0 |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event (AE) data were collected from Day 0 up to Day 30 post-vaccination and solicited reaction (SR) data within 7 days after vaccination. Serious adverse event (SAE) data were collected throughout the study period (up to Day 30 post-vaccination)

Adverse event reporting additional description:

Safety Analysis Set. A SR was an AE that was prelisted (i.e., solicited) in the electronic case report form (eCRF) and considered to be related to vaccination (adverse drug reaction). An unsolicited AE was an observed AE that did not fulfill the conditions prelisted (i.e., solicited) in the eCRF in terms of symptom and/or onset post-vaccination.

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

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 19.0 |

Reporting groups

| | |
|-----------------------|---|
| Reporting group title | South Korea(Group1):MenACYW Conjugate +MMR +Varicella Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | South Korea (Group 2): MenACYW Conjugate Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | South Korea (Group 3): MMR + Varicella Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and Varicella vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine, MMR, vaccine and varicella vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Thailand (Group 11): MenACYW Conjugate Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Thailand (Group 12): MMR + Varicella Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MMR vaccine and varicella vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Groups 1 and10:MenACYW Conjugate Vaccine+MMR+Varicella Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine, MMR vaccine, and varicella vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Groups 2 and 11: MenACYW Conjugate Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Groups 3 and 12: MMR + Varicella Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) from South Korea and Thailand

received single dose of MMR vaccine and varicella vaccine on Day 0.

| | |
|-----------------------|---|
| Reporting group title | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine and DTaP-IPV-HB-Hib vaccine on Day 0.

| | |
|-----------------------|---|
| Reporting group title | Mexico (Group 5): MenACYW Conjugate Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|-----------------------|---|
| Reporting group title | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 23 months) received single dose of DTaP-IPV-HB-Hib Vaccine on Day 0.

| | |
|-----------------------|--|
| Reporting group title | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine |
|-----------------------|--|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of MenACYW Conjugate vaccine and PCV13 vaccine on Day 0.

| | |
|-----------------------|---|
| Reporting group title | Russian Federation (Group 8): MenACYW Conjugate Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 12 to 14 months or 16 to 23 months) received single dose of MenACYW Conjugate vaccine on Day 0.

| | |
|-----------------------|---|
| Reporting group title | Russian Federation (Group 9): PCV13 Vaccine |
|-----------------------|---|

Reporting group description:

Healthy, meningococcal-vaccine naïve toddlers (aged 15 to 23 months) received single dose of PCV13 vaccine on Day 0.

| Serious adverse events | South Korea(Group1):Men ACYW Conjugate +MMR +Varicella | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 103 (5.83%) | 4 / 52 (7.69%) | 2 / 53 (3.77%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Febrile Convulsion | | | |
| subjects affected / exposed | 0 / 103 (0.00%) | 0 / 52 (0.00%) | 0 / 53 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 103 (0.00%) | 0 / 52 (0.00%) | 0 / 53 (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 Bronchiolitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 103 (0.00%) 0 / 0 0 / 0 | 2 / 52 (3.85%) 0 / 2 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Bronchitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 103 (0.00%) 0 / 0 0 / 0 | 1 / 52 (1.92%) 0 / 1 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Bronchitis Viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 2 / 103 (1.94%) 0 / 2 0 / 0 | 0 / 52 (0.00%) 0 / 0 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Croup Infectious subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 103 (0.00%) 0 / 0 0 / 0 | 0 / 52 (0.00%) 0 / 0 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Gastroenteritis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 103 (0.97%) 0 / 1 0 / 0 | 1 / 52 (1.92%) 0 / 1 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Hand-Foot-And-Mouth Disease subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 1 / 103 (0.97%) 0 / 1 0 / 0 | 1 / 52 (1.92%) 0 / 1 0 / 0 | 0 / 53 (0.00%) 0 / 0 0 / 0 |
| Otitis Media Viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 103 (0.00%) 0 / 0 0 / 0 | 0 / 52 (0.00%) 0 / 0 0 / 0 | 1 / 53 (1.89%) 0 / 1 0 / 0 |
| Pneumonia Viral subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all | 0 / 103 (0.00%) 0 / 0 0 / 0 | 0 / 52 (0.00%) 0 / 0 0 / 0 | 1 / 53 (1.89%) 0 / 1 0 / 0 |
| Respiratory Syncytial Virus | | | |

| | | | |
|---|-----------------|----------------|----------------|
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 103 (0.97%) | 0 / 52 (0.00%) | 0 / 53 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 103 (0.97%) | 0 / 52 (0.00%) | 0 / 53 (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 | Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 1 / 42 (2.38%) | 0 / 42 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Febrile Convulsion | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Bronchitis Viral | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Croup Infectious | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 1 / 42 (2.38%) | 0 / 42 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Hand-Foot-And-Mouth Disease | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Otitis Media Viral | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Viral | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Bronchiolitis | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 86 (0.00%) | 0 / 42 (0.00%) | 0 / 42 (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

Groups 1
and10:MenACYW

Groups 2 and 11:
MenACYW Conjugate

Groups 3 and 12:
MMR + Varicella

| | Vaccine+MMR+Varicella Vaccine | Vaccine | Vaccine |
|---|-------------------------------|----------------|----------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 189 (3.17%) | 5 / 94 (5.32%) | 2 / 95 (2.11%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Febrile Convulsion | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 0 / 94 (0.00%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 0 / 94 (0.00%) | 0 / 95 (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 | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 2 / 94 (2.13%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 1 / 94 (1.06%) | 0 / 95 (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 |
| Bronchitis Viral | | | |
| subjects affected / exposed | 2 / 189 (1.06%) | 0 / 94 (0.00%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Croup Infectious | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 1 / 94 (1.06%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 189 (0.53%) | 1 / 94 (1.06%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hand-Foot-And-Mouth Disease | | | |
| subjects affected / exposed | 1 / 189 (0.53%) | 1 / 94 (1.06%) | 0 / 95 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Media Viral | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 0 / 94 (0.00%) | 1 / 95 (1.05%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Viral | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 0 / 94 (0.00%) | 1 / 95 (1.05%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Bronchiolitis | | | |
| subjects affected / exposed | 1 / 189 (0.53%) | 0 / 94 (0.00%) | 0 / 95 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 189 (0.53%) | 0 / 94 (0.00%) | 0 / 95 (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 | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
|---|--|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 1 / 100 (1.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Febrile Convulsion | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 1 / 100 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 1 / 100 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Bronchitis Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Croup Infectious | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Hand-Foot-And-Mouth Disease | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Otitis Media Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Bronchiolitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (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 | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine |
|---|---|--|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Febrile Convulsion | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Asthma | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 | | | |

| | | | |
|---|-----------------|-----------------|----------------|
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Bronchitis Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Croup Infectious | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Hand-Foot-And-Mouth Disease | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Otitis Media Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Viral | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Bronchiolitis | | | |

| | | | |
|---|-----------------|-----------------|----------------|
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (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 |

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

| Non-serious adverse events | South Korea(Group1):Men ACYW Conjugate +MMR +Varicella | South Korea (Group 2): MenACYW Conjugate Vaccine | South Korea (Group 3): MMR + Varicella Vaccine |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 85 / 103 (82.52%) | 43 / 52 (82.69%) | 37 / 53 (69.81%) |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 17 / 103 (16.50%) | 8 / 52 (15.38%) | 9 / 53 (16.98%) |
| occurrences (all) | 17 | 8 | 9 |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 21 / 103 (20.39%) | 9 / 52 (17.31%) | 6 / 53 (11.32%) |
| occurrences (all) | 21 | 9 | 6 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 35 / 103 (33.98%) | 20 / 52 (38.46%) | 8 / 53 (15.09%) |
| occurrences (all) | 60 | 20 | 10 |
| Injection Site Pain | | | |
| subjects affected / exposed | 31 / 103 (30.10%) | 15 / 52 (28.85%) | 12 / 53 (22.64%) |
| occurrences (all) | 72 | 15 | 21 |
| Injection Site Swelling | | | |
| subjects affected / exposed | 25 / 103 (24.27%) | 14 / 52 (26.92%) | 3 / 53 (5.66%) |
| occurrences (all) | 35 | 14 | 3 |
| Pyrexia | | | |
| subjects affected / exposed | 21 / 103 (20.39%) | 11 / 52 (21.15%) | 10 / 53 (18.87%) |
| occurrences (all) | 21 | 12 | 12 |
| Gastrointestinal disorders | | | |

| | | | |
|--|-------------------------|------------------------|------------------------|
| Diarrhoea subjects affected / exposed occurrences (all) | 3 / 103 (2.91%) 3 | 2 / 52 (3.85%) 2 | 0 / 53 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 7 / 103 (6.80%) 7 | 3 / 52 (5.77%) 3 | 2 / 53 (3.77%) 2 |
| Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) | 3 / 103 (2.91%) 3 | 0 / 52 (0.00%) 0 | 5 / 53 (9.43%) 5 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 1 / 103 (0.97%) 1 | 3 / 52 (5.77%) 3 | 4 / 53 (7.55%) 4 |
| Psychiatric disorders Irritability subjects affected / exposed occurrences (all) | 31 / 103 (30.10%) 31 | 12 / 52 (23.08%) 12 | 11 / 53 (20.75%) 11 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 4 / 103 (3.88%) 4 | 1 / 52 (1.92%) 1 | 4 / 53 (7.55%) 5 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 29 / 103 (28.16%) 37 | 17 / 52 (32.69%) 23 | 13 / 53 (24.53%) 18 |
| Pharyngitis subjects affected / exposed occurrences (all) | 1 / 103 (0.97%) 1 | 2 / 52 (3.85%) 2 | 3 / 53 (5.66%) 4 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 103 (0.00%) 0 | 1 / 52 (1.92%) 1 | 0 / 53 (0.00%) 0 |
| Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 6 / 103 (5.83%) 7 | 3 / 52 (5.77%) 3 | 0 / 53 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased Appetite | | | |

| | | | |
|-----------------------------|-------------------|------------------|-----------------|
| subjects affected / exposed | 29 / 103 (28.16%) | 10 / 52 (19.23%) | 8 / 53 (15.09%) |
| occurrences (all) | 29 | 10 | 8 |

| Non-serious adverse events | Thailand (Group 10):MenACYW Conjugate + MMR+ Varicella Vaccine | Thailand (Group 11): MenACYW Conjugate Vaccine | Thailand (Group 12): MMR + Varicella Vaccine |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 52 / 86 (60.47%) | 33 / 42 (78.57%) | 34 / 42 (80.95%) |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 8 / 86 (9.30%) | 7 / 42 (16.67%) | 7 / 42 (16.67%) |
| occurrences (all) | 8 | 7 | 7 |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 15 / 86 (17.44%) | 14 / 42 (33.33%) | 12 / 42 (28.57%) |
| occurrences (all) | 15 | 14 | 12 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 22 / 86 (25.58%) | 6 / 42 (14.29%) | 7 / 42 (16.67%) |
| occurrences (all) | 51 | 6 | 12 |
| Injection Site Pain | | | |
| subjects affected / exposed | 26 / 86 (30.23%) | 15 / 42 (35.71%) | 18 / 42 (42.86%) |
| occurrences (all) | 57 | 15 | 30 |
| Injection Site Swelling | | | |
| subjects affected / exposed | 15 / 86 (17.44%) | 5 / 42 (11.90%) | 4 / 42 (9.52%) |
| occurrences (all) | 35 | 5 | 7 |
| Pyrexia | | | |
| subjects affected / exposed | 6 / 86 (6.98%) | 3 / 42 (7.14%) | 4 / 42 (9.52%) |
| occurrences (all) | 6 | 3 | 4 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 86 (1.16%) | 0 / 42 (0.00%) | 0 / 42 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 6 / 86 (6.98%) | 4 / 42 (9.52%) | 6 / 42 (14.29%) |
| occurrences (all) | 6 | 4 | 6 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|--|------------------------|------------------------|------------------------|
| Cough subjects affected / exposed occurrences (all) | 0 / 86 (0.00%) 0 | 0 / 42 (0.00%) 0 | 0 / 42 (0.00%) 0 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 0 / 86 (0.00%) 0 | 0 / 42 (0.00%) 0 | 0 / 42 (0.00%) 0 |
| Psychiatric disorders Irritability subjects affected / exposed occurrences (all) | 14 / 86 (16.28%) 15 | 11 / 42 (26.19%) 11 | 14 / 42 (33.33%) 14 |
| Infections and infestations Bronchitis subjects affected / exposed occurrences (all) | 1 / 86 (1.16%) 1 | 0 / 42 (0.00%) 0 | 1 / 42 (2.38%) 1 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 5 / 86 (5.81%) 5 | 3 / 42 (7.14%) 4 | 6 / 42 (14.29%) 7 |
| Pharyngitis subjects affected / exposed occurrences (all) | 2 / 86 (2.33%) 2 | 1 / 42 (2.38%) 1 | 2 / 42 (4.76%) 2 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 86 (0.00%) 0 | 0 / 42 (0.00%) 0 | 1 / 42 (2.38%) 1 |
| Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 3 / 86 (3.49%) 3 | 2 / 42 (4.76%) 2 | 4 / 42 (9.52%) 4 |
| Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all) | 11 / 86 (12.79%) 11 | 12 / 42 (28.57%) 12 | 5 / 42 (11.90%) 5 |

| Non-serious adverse events | Groups 1 and 10: MenACYW Conjugate Vaccine + MMR + Varicella Vaccine | Groups 2 and 11: MenACYW Conjugate Vaccine | Groups 3 and 12: MMR + Varicella Vaccine |
|---|--|--|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 137 / 189 (72.49%) | 76 / 94 (80.85%) | 71 / 95 (74.74%) |
| Nervous system disorders | | | |

| | | | |
|---|--------------------------|------------------------|------------------------|
| Somnolence subjects affected / exposed occurrences (all) | 25 / 189 (13.23%) 25 | 15 / 94 (15.96%) 15 | 16 / 95 (16.84%) 16 |
| General disorders and administration site conditions | | | |
| Crying subjects affected / exposed occurrences (all) | 36 / 189 (19.05%) 36 | 23 / 94 (24.47%) 23 | 18 / 95 (18.95%) 18 |
| Injection Site Erythema subjects affected / exposed occurrences (all) | 57 / 189 (30.16%) 111 | 26 / 94 (27.66%) 26 | 15 / 95 (15.79%) 22 |
| Injection Site Pain subjects affected / exposed occurrences (all) | 57 / 189 (30.16%) 129 | 30 / 94 (31.91%) 30 | 30 / 95 (31.58%) 51 |
| Injection Site Swelling subjects affected / exposed occurrences (all) | 40 / 189 (21.16%) 70 | 19 / 94 (20.21%) 19 | 7 / 95 (7.37%) 10 |
| Pyrexia subjects affected / exposed occurrences (all) | 27 / 189 (14.29%) 27 | 14 / 94 (14.89%) 15 | 14 / 95 (14.74%) 16 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 4 / 189 (2.12%) 4 | 2 / 94 (2.13%) 2 | 0 / 95 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 13 / 189 (6.88%) 13 | 7 / 94 (7.45%) 7 | 8 / 95 (8.42%) 8 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough subjects affected / exposed occurrences (all) | 3 / 189 (1.59%) 3 | 0 / 94 (0.00%) 0 | 5 / 95 (5.26%) 5 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 1 / 189 (0.53%) 1 | 3 / 94 (3.19%) 3 | 4 / 95 (4.21%) 4 |
| Psychiatric disorders | | | |
| Irritability | | | |

| | | | |
|--|-------------------------|------------------------|------------------------|
| subjects affected / exposed occurrences (all) | 45 / 189 (23.81%) 46 | 23 / 94 (24.47%) 23 | 25 / 95 (26.32%) 25 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 5 / 189 (2.65%) | 1 / 94 (1.06%) | 5 / 95 (5.26%) |
| occurrences (all) | 5 | 1 | 6 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 34 / 189 (17.99%) | 20 / 94 (21.28%) | 19 / 95 (20.00%) |
| occurrences (all) | 42 | 27 | 25 |
| Pharyngitis | | | |
| subjects affected / exposed | 3 / 189 (1.59%) | 3 / 94 (3.19%) | 5 / 95 (5.26%) |
| occurrences (all) | 3 | 3 | 6 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 189 (0.00%) | 1 / 94 (1.06%) | 1 / 95 (1.05%) |
| occurrences (all) | 0 | 1 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 9 / 189 (4.76%) | 5 / 94 (5.32%) | 4 / 95 (4.21%) |
| occurrences (all) | 10 | 5 | 4 |
| Metabolism and nutrition disorders | | | |
| Decreased Appetite | | | |
| subjects affected / exposed | 40 / 189 (21.16%) | 22 / 94 (23.40%) | 13 / 95 (13.68%) |
| occurrences (all) | 40 | 22 | 13 |

| Non-serious adverse events | Mexico (Group 4): MenACYW Conjugate + DTaP-IPV-HB-Hib Vaccine | Mexico (Group 5): MenACYW Conjugate Vaccine | Mexico (Group 6): DTaP-IPV-HB-Hib Vaccine |
|--|--|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 142 / 200 (71.00%) | 65 / 100 (65.00%) | 85 / 100 (85.00%) |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 31 / 200 (15.50%) | 15 / 100 (15.00%) | 17 / 100 (17.00%) |
| occurrences (all) | 31 | 15 | 17 |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 46 / 200 (23.00%) | 25 / 100 (25.00%) | 26 / 100 (26.00%) |
| occurrences (all) | 46 | 25 | 26 |
| Injection Site Erythema | | | |

| | | | |
|---|--------------------------|-------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 67 / 200 (33.50%) 96 | 15 / 100 (15.00%) 15 | 37 / 100 (37.00%) 37 |
| Injection Site Pain subjects affected / exposed occurrences (all) | 87 / 200 (43.50%) 148 | 27 / 100 (27.00%) 27 | 54 / 100 (54.00%) 54 |
| Injection Site Swelling subjects affected / exposed occurrences (all) | 52 / 200 (26.00%) 68 | 8 / 100 (8.00%) 8 | 30 / 100 (30.00%) 30 |
| Pyrexia subjects affected / exposed occurrences (all) | 35 / 200 (17.50%) 35 | 8 / 100 (8.00%) 8 | 17 / 100 (17.00%) 17 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 12 / 200 (6.00%) 13 | 5 / 100 (5.00%) 6 | 6 / 100 (6.00%) 6 |
| Vomiting subjects affected / exposed occurrences (all) | 16 / 200 (8.00%) 17 | 7 / 100 (7.00%) 7 | 9 / 100 (9.00%) 9 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough subjects affected / exposed occurrences (all) | 5 / 200 (2.50%) 5 | 3 / 100 (3.00%) 3 | 2 / 100 (2.00%) 2 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 1 / 200 (0.50%) 1 | 0 / 100 (0.00%) 0 | 1 / 100 (1.00%) 1 |
| Psychiatric disorders | | | |
| Irritability subjects affected / exposed occurrences (all) | 64 / 200 (32.00%) 64 | 34 / 100 (34.00%) 34 | 33 / 100 (33.00%) 33 |
| Infections and infestations | | | |
| Bronchitis subjects affected / exposed occurrences (all) | 0 / 200 (0.00%) 0 | 0 / 100 (0.00%) 0 | 0 / 100 (0.00%) 0 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 29 / 200 (14.50%) 31 | 18 / 100 (18.00%) 18 | 15 / 100 (15.00%) 16 |

| | | | |
|------------------------------------|-------------------|-------------------|-------------------|
| Pharyngitis | | | |
| subjects affected / exposed | 9 / 200 (4.50%) | 6 / 100 (6.00%) | 4 / 100 (4.00%) |
| occurrences (all) | 9 | 6 | 4 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 100 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 200 (3.00%) | 1 / 100 (1.00%) | 0 / 100 (0.00%) |
| occurrences (all) | 6 | 1 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased Appetite | | | |
| subjects affected / exposed | 51 / 200 (25.50%) | 25 / 100 (25.00%) | 20 / 100 (20.00%) |
| occurrences (all) | 51 | 25 | 20 |

| Non-serious adverse events | Russian Federation (Group7): MenACYW Conjugate + PCV13 Vaccine | Russian Federation (Group 8): MenACYW Conjugate Vaccine | Russian Federation (Group 9): PCV13 Vaccine |
|---|--|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 75 / 200 (37.50%) | 30 / 100 (30.00%) | 17 / 99 (17.17%) |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 25 / 200 (12.50%) | 6 / 100 (6.00%) | 4 / 99 (4.04%) |
| occurrences (all) | 25 | 6 | 4 |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 8 / 200 (4.00%) | 4 / 100 (4.00%) | 2 / 99 (2.02%) |
| occurrences (all) | 8 | 4 | 2 |
| Injection Site Erythema | | | |
| subjects affected / exposed | 55 / 200 (27.50%) | 17 / 100 (17.00%) | 8 / 99 (8.08%) |
| occurrences (all) | 91 | 17 | 8 |
| Injection Site Pain | | | |
| subjects affected / exposed | 37 / 200 (18.50%) | 8 / 100 (8.00%) | 9 / 99 (9.09%) |
| occurrences (all) | 62 | 8 | 9 |
| Injection Site Swelling | | | |
| subjects affected / exposed | 21 / 200 (10.50%) | 7 / 100 (7.00%) | 2 / 99 (2.02%) |
| occurrences (all) | 27 | 7 | 2 |
| Pyrexia | | | |

| | | | |
|--|------------------------|----------------------|---------------------|
| subjects affected / exposed occurrences (all) | 13 / 200 (6.50%) 13 | 3 / 100 (3.00%) 3 | 2 / 99 (2.02%) 3 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 1 / 100 (1.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 1 / 200 (0.50%) | 1 / 100 (1.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 26 / 200 (13.00%) | 16 / 100 (16.00%) | 9 / 99 (9.09%) |
| occurrences (all) | 26 | 16 | 9 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 200 (0.50%) | 0 / 100 (0.00%) | 1 / 99 (1.01%) |
| occurrences (all) | 1 | 0 | 1 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 2 / 200 (1.00%) | 1 / 100 (1.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 3 / 200 (1.50%) | 6 / 100 (6.00%) | 1 / 99 (1.01%) |
| occurrences (all) | 3 | 6 | 1 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 200 (0.00%) | 0 / 100 (0.00%) | 0 / 99 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|------------------------------------|------------------|-------------------|----------------|
| Metabolism and nutrition disorders | | | |
| Decreased Appetite | | | |
| subjects affected / exposed | 19 / 200 (9.50%) | 12 / 100 (12.00%) | 7 / 99 (7.07%) |
| occurrences (all) | 19 | 12 | 7 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-------------------|---|
| 11 July 2016 | Following amendment changes were made: Identified the Coordinating Investigator for each country, provided available Health Authority file numbers and update of Regional Clinical Trial Manager information; revised to anticipate the need to potentially include additional sites in South Korea; Visit 0 including activities performed were added for subjects in the Russian Federation; primary endpoint measurement was changed so that it was measured by hSBA instead of rSBA and the definition of hSBA in the primary objective was updated; included screening criteria for the subjects in the Russian Federation; neurological examinations were added according to the recommendations of Russian Health Authorities; updated the planned trial calendar; provided specific labeling information; and updated wording so that Abs to diphtheria, inactivated polio, hepatitis B and Haemophilus influenzae antigens would not be measured before vaccination. |
| 05 May 2017 | Following amendment changes were made: Updated to expand the age range of toddlers in Russia who were eligible to receive the 3rd dose of PCV13 vaccine as part of the Russian National Immunization program; specified for pertussis antigens; clarified timing of the 2nd dose of PCV13; included hepatitis B Ab level threshold of 100 mIU/mL for reliable prediction of long-term protection against hepatitis B virus; clarified that only tetanus and pertussis antigens would be tested before and 30 days after vaccination; and defined the end of the trial period as when the last assay results were available and updated trial calendar. |
| 11 September 2017 | Following amendment changes were made: Updated protocol to include Thailand as well as information pertaining to Thailand (including but not limited to Principal Investigators, number of sites, number of subjects planned to be enrolled, age of subjects, reporting requirements for SAEs in Thailand) as the study would also be conducted there; updated the number of subjects planned to be enrolled in South Korea; clarified the number of subjects in each group that would have the Ab responses to the meningococcal serogroups A, C, Y, and W measured by rSBA for the observational objective; specified the serostatus cutoffs for Abs to the antigens contained in MMR vaccine and Varicella vaccine based on the assays that were to be used for the analysis; and updated the definition of pertussis vaccine response specific for the booster vaccination response in order to make the definition specific to the manner the vaccine was being used in the study. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported