# Clinical trial results:
# A phase 3 open-label study to evaluate the immunogenicity and safety of a mixed (HEXA/PENTA/HEXA) primary series schedule that includes V419 (PR5I) at 2 and 6 months of age and Pediacel at 4 months of age.

## Summary

| | |
|---|---|
| EudraCT number | 2012-004221-25 |
| Trial protocol | ES |
| Global end of trial date | 19 March 2014 |

### Results information

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 01 June 2019 |
| First version publication date | 27 May 2015 |
| Version creation reason | |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | V419-010 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01839188 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Merck Protocol Number: V419-010, MCMVaccBV Protocol ID: PRI02C |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Merck Sharp & Dohme Corp. |
| Sponsor organisation address | 2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com |

Notes:

### Paediatric regulatory details

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 19 March 2014 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 19 March 2014 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the immune response and the safety of a primary series schedule that includes V419 (PR5I) at 2 and 6 months of age and Pediacel at 4 months of age. Primary objectives of this study were 1) to demonstrate that the mixed schedule induces acceptable responses for Hepatitis B (HB) one month after completion of the mixed schedule; and 2) to demonstrate that the mixed schedule induces acceptable responses for Haemophilus influenza type b (Hib) one month after completion of the mixed schedule. Secondary objectives of this study were: 1) to describe the antibody response to all PR5I antigens one month after completion of the mixed schedule; 2) to describe the antibody response to meningococcal serogroup C (MCC) conjugate vaccine one month after the second dose of MenC vaccine; and 3) to describe the safety profile after each dose of study vaccines administered.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research. The following additional measures defined for this individual study were in place for the protection of trial subjects:

Subjects in the study received the study vaccines (PR5I and Pediacel®) in line with the recommended infant immunisation schedule in Spain, and the immunisation schedule was consistent with other paediatric vaccines routinely given at the same age. NeisVac-C®, Prevenar 13®, and RotaTeq® were administered in accordance with their respective Summary of Product Characteristics. Subjects with allergy to any of the vaccine components or history of a life-threatening reaction to a vaccine containing the same substances as the study vaccines (including concomitants) were not vaccinated. Vaccines were administered by qualified study personnel. After each vaccination, subjects were kept under observation for 30 minutes to ensure their safety. Adequate treatment provisions, including epinephrine, were available for immediate use, should an anaphylactic or anaphylactoid reaction occur.

Background therapy:

Infants were previously vaccinated with only 1 dose of monovalent Hepatitis B vaccine, within the 3 days after birth, outside of the study context.

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 01 May 2013 |
| 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 | Spain: 385 |
| Worldwide total number of subjects | 385 |
| EEA total number of subjects | 385 |

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) | 385 |
| 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:

The study enrolled N=385 infant participants previously vaccinated with only 1 dose of monovalent Hepatitis B vaccine, within 3 days after birth, outside of study context.

### Pre-assignment

Screening details:

Participants progressed through the study as a single group, with all participants receiving the same mixed-schedule vaccination series. Vaccination (V1) was administered on Study Day 0 (2 months of age), with V2 (4 months of age) and V3 (6 months of age) administered at Study Months 2 and 4, respectively.

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | PR5I (V1); Pediacel® (V2); PR5I (V3) |

Arm description:

[Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | PR5I |
| Investigational medicinal product code | |
| Other name | V419; Vaxelis®; DTaP-HBIPV-Hib |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Hexavalent PR5I vaccine (DTaPHB-IPV-Hib = Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed [DTaP], Hepatitis B [HB; Recombinant DNA], Inactivated Poliovirus [IPV], and Haemophilus influenzae type b [Hib] conjugate vaccine [adsorbed]) at 0.5 mL for IM injection (left upper thigh) at 2 and 6 months of age.

| | |
|---|---|
| Investigational medicinal product name | Pediacel® |
| Investigational medicinal product code | |
| Other name | DTaP-IPV-Hib |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Pentavalent Pediacel® vaccine (DTaPIPV-Hib = Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed [DTaP], Inactivated Poliovirus [IPV], and Haemophilus influenzae type b [Hib] conjugate vaccine [adsorbed]) at 0.5 mL for IM injection (left upper thigh) at 4 months of age.

| | |
|---|---|
| Investigational medicinal product name | RotaTeq® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Oral solution in single-dose container |
| Routes of administration | Intramuscular use, Oral use |

Dosage and administration details:

Human-bovine rotavirus reassortants (live) vaccine 2 mL oral administration at 2, 4 and 6 months of age. RotaTeq® administered prior to any other vaccine administration to avoid having the infant participants spit up the RotaTeq® when crying.

| | |
|---|---|
| Investigational medicinal product name | NeisVac-C® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Meningococcal group C (MCC) polysaccharide conjugate vaccine (adsorbed) at 0.5 mL for IM injection (right upper thigh) at 2 and 4 months of age.

| | |
|---|---|
| Investigational medicinal product name | Prevenar 13® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Pneumococcal polysaccharide conjugate vaccine [PCV; 13-valent, adsorbed]) at 0.5 mL for IM injection (right upper thigh) at 2 and 4 months of age.

| **Number of subjects in period 1** | PR5I (V1); Pediacel® (V2); PR5I (V3) |
|---|---|
| Started | 385 |
| Treated | 385 |
| Completed | 384 |
| Not completed | 1 |
| Consent withdrawn by subject | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | PR5I (V1); Pediacel® (V2); PR5I (V3) |
| Reporting group description: | |
| [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |

| Reporting group values | PR5I (V1); Pediacel® (V2); PR5I (V3) | Total | |
|---|---|---|---|
| Number of subjects | 385 | 385 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 385 | 385 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age Continuous<br>Units: Days | | | |
| arithmetic mean | 60.72 | | |
| standard deviation | ± 7.75 | - | |
| Sex: Female, Male<br>Units: Subjects | | | |
| Female | 199 | 199 | |
| Male | 186 | 186 | |
| Body Weight<br>Units: kg | | | |
| arithmetic mean | 5.14 | | |
| standard deviation | ± 0.59 | - | |

| Subject analysis sets | |
|---|---|
| Subject analysis set title | PR5I (V1) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 2 months of age. | |
| Subject analysis set title | Pediacel® (V2) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: | |
| [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |

| | |
|---|---|
| Subject analysis set title | PR5I (V3) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |
| Subject analysis set title | PR5I (V1) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 2 months of age. | |
| Subject analysis set title | Pediacel® (V2) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |
| Subject analysis set title | PR5I (V3) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |
| Subject analysis set title | PR5I (V1); Pediacel® (V2) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |

| **Reporting group values** | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|
| Number of subjects | 384 | 383 | 383 |
| Age categorical<br>Units: Subjects | | | |
| In utero<br>Preterm newborn infants (gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23 months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over | | | |
| Age Continuous<br>Units: Days<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Sex: Female, Male<br>Units: Subjects | | | |
| Female<br>Male | | | |
| Body Weight<br>Units: kg<br>arithmetic mean<br>standard deviation | ± | ± | ± |

| Reporting group values | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|
| Number of subjects | 385 | 385 | 384 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | |
| Preterm newborn infants (gestational age < 37 wks) | | | |
| Newborns (0-27 days) | | | |
| Infants and toddlers (28 days-23 months) | | | |
| Children (2-11 years) | | | |
| Adolescents (12-17 years) | | | |
| Adults (18-64 years) | | | |
| From 65-84 years | | | |
| 85 years and over | | | |
| Age Continuous | | | |
| Units: Days | | | |
| arithmetic mean | | | |
| standard deviation | ± | ± | ± |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | | | |
| Male | | | |
| Body Weight | | | |
| Units: kg | | | |
| arithmetic mean | | | |
| standard deviation | ± | ± | ± |

| Reporting group values | PR5I (V1); Pediacel® (V2) | | |
|---|---|---|---|
| Number of subjects | 385 | | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | |
| Preterm newborn infants (gestational age < 37 wks) | | | |
| Newborns (0-27 days) | | | |
| Infants and toddlers (28 days-23 months) | | | |
| Children (2-11 years) | | | |
| Adolescents (12-17 years) | | | |
| Adults (18-64 years) | | | |
| From 65-84 years | | | |
| 85 years and over | | | |
| Age Continuous | | | |
| Units: Days | | | |
| arithmetic mean | | | |
| standard deviation | ± | | |
| Sex: Female, Male | | | |
| Units: Subjects | | | |
| Female | | | |
| Male | | | |

| | | | |
|---|---|---|---|
| Body Weight<br>Units: kg<br>arithmetic mean<br>standard deviation | ± | | |

## End points reporting groups

| | |
|---|---|
| Reporting group title | PR5I (V1); Pediacel® (V2); PR5I (V3) |
| Reporting group description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |
| Subject analysis set title | PR5I (V1) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 2 months of age. | |
| Subject analysis set title | Pediacel® (V2) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |
| Subject analysis set title | PR5I (V3) |
| Subject analysis set type | Sub-group analysis |
| Subject analysis set description: [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |
| Subject analysis set title | PR5I (V1) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 2 months of age. | |
| Subject analysis set title | Pediacel® (V2) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |
| Subject analysis set title | PR5I (V3) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age. | |
| Subject analysis set title | PR5I (V1); Pediacel® (V2) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: [Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. | |

## Primary: Percentage of Participants with an Anti-Hepatitis B Surface Antigen (HBsAg) Antibody Titer ≥ 10 mIU/mL

| | |
|---|---|
| End point title | Percentage of Participants with an Anti-Hepatitis B Surface Antigen (HBsAg) Antibody Titer ≥ 10 mIU/mL[1] |
| End point description: The percentage of participants with an anti-HBsAg antibody titer ≥ 10 mill-International Units/mL (mIU/mL) was assessed. Participant serum samples were collected for analysis with an enhanced chemiluminescence assay to determine the concentration of antibodies to HBsAg. Analysis Population: all participants receiving ≥ 1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint. | |
| End point type | Primary |

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

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: This is a single arm study, subjects were all enrolled in the same treatment group. The success of the study required that the primary objective was achieved for both Hepatitis B and PRP. For Hepatitis B, the immune response to PR5I vaccine was considered as acceptable if the lower bound of the 2-sided 95% CI of the % of subjects with anti-HBs titre ≥10 mIU/mL one month after the third dose of the mixed schedule was greater than 90%.

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 369 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 98.9 (97.2 to 99.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Percentage of Participants with an Anti-Polyribosylribitol Phosphate (PRP) Antibody Titer ≥ 0.15 µg/mL

| End point title | Percentage of Participants with an Anti-Polyribosylribitol Phosphate (PRP) Antibody Titer ≥ 0.15 µg/mL[2] |
|---|---|

End point description:

The percentage of participants with an anti-Polyribosylribitol Phosphate (PRP) antibody titer ≥ 0.15 µg/mL was assessed. Participant serum samples were collected for analysis by radioimmunoassay to determine the concentration of antibodies to PRP, a Haemophilus influenzae type b (Hib) capsular polysaccharide. Analysis Population: all participants receiving ≥ 1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

Notes:

[2] - 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: This is a single arm study, subjects were all enrolled in the same treatment group. The success of the study required that the primary objective was achieved for both Hepatitis B and PRP. For Hib (PRP), the immune response to PR5I vaccine was considered as acceptable if the lower bound of the 2-sided 95% CI of the % of subjects with anti-PRP titre ≥0.15 µg/mL one month after the third dose of the mixed schedule was greater than 80%.

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 365 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 100.0 (99.0 to 100.0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentration of Antibodies to Hepatitis B Surface Antigen (HBsAg)

| End point title | Geometric Mean Concentration of Antibodies to Hepatitis B Surface Antigen (HBsAg) |
|---|---|

End point description:

Participant serum samples were collected for analysis with an enhanced chemiluminescence assay to determine the geometric mean concentration of antibodies to Hepatitis B Surface Antigen (HBsAg). The unit of measure is milli International Units/mL (mIU/mL). Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 369 | | | |
| Units: mIU/mL | | | | |
| geometric mean (confidence interval 95%) | 1054.97 (911.49 to 1221.03) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentration of Antibodies to Polyribosylribitol Phosphate (PRP) Antigen

| End point title | Geometric Mean Concentration of Antibodies to Polyribosylribitol Phosphate (PRP) Antigen |
|---|---|

End point description:

Participant serum samples were collected for analysis by radioimmunoassay (RIA) to determine the geometric mean concentration of antibodies to polyribosylribitol phosphate (PRP), a Haemophilus influenzae type b (Hib) capsular polysaccharide. Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 365 | | | |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | 8.00 (7.17 to 8.93) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentration of Antibodies to Diphtheria Toxin

| End point title | Geometric Mean Concentration of Antibodies to Diphtheria Toxin |
|---|---|

End point description:

Participant serum samples were collected for analysis with a Micrometabolic Inhibition Test (MIT) to determine the geometric mean concentration of neutralizing antibodies to diphtheria toxin. The unit of measure is International Units/mL (IU/mL). Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 359 | | | |
| Units: IU/mL | | | | |
| geometric mean (confidence interval 95%) | 0.47 (0.42 to 0.52) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentration of Antibodies to Tetanus Toxin

| End point title | Geometric Mean Concentration of Antibodies to Tetanus Toxin |
|---|---|

End point description:

Participant serum samples were collected for analysis by Enzyme-linked Immunosorbent Assay (ELISA) to determine the geometric mean concentration of antibodies to tetanus toxin. The unit of measure is International Units/mL (IU/mL). Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 350 | | | |
| Units: IU/mL | | | | |
| geometric mean (confidence interval 95%) | 2.44 (2.31 to 2.59) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentrations of Antibodies to Pertussis Antigens

| End point title | Geometric Mean Concentrations of Antibodies to Pertussis Antigens |
|---|---|

End point description:

Participant serum samples were collected for analysis by ELISA to determine the geometric mean concentration of antibodies (Abs) to the following Pertussis antigens: pertussis toxoid (PT), filamentous hemagglutinin (FHA), pertactin (PRN) and fimbriae types (FIM) 2&3. The unit of measure is ELISA Units/mL (EU/mL). Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 349 | | | |
| Units: EU/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|---|---|---|---|---|
| Anti-PT Abs | 107.46 (101.55 to 113.71) | | | |
| Anti-FHA Abs | 67.09 (62.38 to 72.15) | | | |
| Anti-PRN Abs | 56.46 (51.60 to 61.78) | | | |
| Anti-FIM 2&3 Abs | 360.99 (332.58 to 391.82) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Titers for Antibodies to Inactivated Poliovirus 1-3 (IPV1-3)

| | |
|---|---|
| End point title | Geometric Mean Titers for Antibodies to Inactivated Poliovirus 1-3 (IPV1-3) |

End point description:

Participant serum samples were collected for analysis with a Micrometabolic Inhibition Test (MIT) to determine the geometric mean titer of neutralizing antibodies (Abs) to Inactivated Poliovirus 1, 2, & 3 (IPV1, IPV2, & IPV3). The unit of measure is titer, expressed as the reciprocal dilution of the highest dilution that neutralizes 50% of the challenge virus. Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 356 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-IPV1 Abs | 663.97 (588.10 to 749.62) | | | |
| Anti-IPV2 Abs | 1198.93 (1051.90 to 1366.51) | | | |
| Anti-IPV3 Abs | 764.64 (664.70 to 879.61) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants Responding to Polyribosylribitol Phosphate (PRP) Antigen, Diptheria Toxin (D), Tetanus Toxin (T), and Inactivated Poliovirus 1, 2, & 3 (IPV1, IPV2, & IPV3)

| End point title | Percentage of Participants Responding to Polyribosylribitol Phosphate (PRP) Antigen, Diptheria Toxin (D), Tetanus Toxin (T), and Inactivated Poliovirus 1, 2, & 3 (IPV1, IPV2, & IPV3) |
|---|---|

End point description:

Participants were considered as responding if the observed concentration or titer for antibodies (Abs) to specific antigens exceeded the following thresholds:

1) For anti-PRP Abs (Hib capsular polysaccharide) – Response defined as a concentration ≥1 µg/mL (measured by RIA);
2) For anti-D Abs – Response defined at 2 concentrations: ≥0.01 IU/mL and ≥0.10 IU/mL (measured by MIT);
3) For anti-T Abs – Response defined at 2 concentrations: ≥0.01 IU/mL and ≥0.10 IU/mL (measured by ELISA);
4) For anti-IPV1, anti-IPV2, and anti-IPV3 Abs – Response defined as a titer ≥ 8 (measured by MIT).

The percentage of participants considered as responding to the individual antigen (per the response threshold[s]) were assessed. Analysis Population: All participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 5 (one month after receiving Vaccination 3)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 370 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | | | | |
| Anti-PRP Ab ≥ 1 µg/mL | 95.3 (92.6 to 97.3) | | | |
| Anti-Diptheria Ab ≥0.01 IU/mL | 100.0 (99.0 to 100.0) | | | |
| Anti-Diptheria Ab ≥0.10 IU/mL | 92.2 (88.9 to 94.8) | | | |
| Anti-Tetanus ≥0.01 IU/mL | 100.0 (99.0 to 100.0) | | | |
| Anti-Tetanus Ab ≥0.10 IU/mL | 100.0 (99.0 to 100.0) | | | |
| Anti-IPV1 Ab Titer ≥8 | 100.0 (99.0 to 100.0) | | | |
| Anti-IPV2 Ab Titer ≥8 | 100.0 (99.0 to 100.0) | | | |
| Anti-IPV3 Ab Titer ≥8 | 100.0 (99.0 to 100.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Titer of Anti-Meningococcal Group C Polysaccharide Conjugate (MCC) Antibodies

| End point title | Geometric Mean Titer of Anti-Meningococcal Group C Polysaccharide Conjugate (MCC) Antibodies |
|---|---|

End point description:

Participant serum samples were collected to determine the geometric mean titer of anti-MCC antibodies, measured by the Serum Bactericidal Antibody assay using rabbit complement (rSBA). The unit of measure is titer, expressed as the reciprocal of the final serum dilution giving ≥50% killing of the challenge bacterial strain. Analysis Population: all participants receiving ≥1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 3 (one month after receiving Vaccination 2)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 375 | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | 739.63 (659.94 to 828.96) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with an Anti-Meningococcal Group C Polysaccharide Conjugate (MCC) Antibody Titer ≥ 8

| End point title | Percentage of Participants with an Anti-Meningococcal Group C Polysaccharide Conjugate (MCC) Antibody Titer ≥ 8 |
|---|---|

End point description:

The percentage of participants with an anti-MCC antibody titer ≥ 8 was assessed. Participant serum samples were collected and analyzed for anti-MCC antibodies with the Serum Bactericidal Antibody assay using rabbit complement (rSBA). Analysis Population: all participants receiving ≥ 1 dose of study vaccination without protocol deviation, having post-vaccination immunogenicity data available for the evaluation of the respective analysis endpoint.

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

End point timeframe:

Month 3 (one month after receiving Vaccination 2)

| End point values | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 375 | | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 99.2 (97.7 to 99.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with a Body Temperature ≥ 38°C after Each Vaccination

| End point title | Percentage of Participants with a Body Temperature ≥ 38°C after Each Vaccination |
|---|---|

End point description:

The percentage of participants with a body temperature ≥ 38.0°C from Day 1 to Day 5 after each vaccination was assessed. Per protocol, the participant's parent(s)/legal representative recorded daily body temperature measurements each evening by the axillary route (N=3 collected via rectal route; N=1 collected via oral route) and recorded these observations on the Vaccine Report Card (VRC). Temperatures were based on actual temperatures recorded with no adjustments for the route of assessment. Analysis Population: all participants receiving ≥ 1 dose of any vaccination with corresponding safety follow-up data, having available body temperature data.

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

End point timeframe:

Up to Day 5 following each vaccination

| End point values | PR5I (V1) | Pediacel® (V2) | PR5I (V3) | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 384 | 383 | 383 | |
| Units: Percentage of Participants | | | | |
| number (not applicable) | 4.9 | 6.3 | 4.7 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Experiencing a Solicited Injection Site Reaction (ISR) Related to the PR5I/Pediacel® Vaccination

| End point title | Number of Participants Experiencing a Solicited Injection Site Reaction (ISR) Related to the PR5I/Pediacel® Vaccination |
|---|---|

End point description:

The number of participants experiencing solicited ISRs related to the PRI5 or Pediacel® vaccination was assessed. Solicited ISRs (erythema, pain and swelling) occurring at the PR5I or Pediacel® injection site were always considered related to the PR5I or Pediacel® vaccine, respectively. All AEs/ISRs were

recorded on the VRC by the participant's parent(s)/legal representative. Data are presented for the number of participants experiencing solicited ISRs up to Day 5 after each vaccination and after any vaccination. Analysis Population: All participants receiving ≥1 dose of PR5I/Pediacel® vaccination with corresponding safety follow-up data after each vaccination (for V1, V2, and V3 arms) and after any vaccination (for overall V1; V2; V3 arm) with PR5I/Pediacel®.

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

End point timeframe:

Up to Day 5 following each vaccination

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 385 | 385 | 385 | 384 |
| Units: Participants | | | | |
| Injection-site erythema | 136 | 81 | 65 | 69 |
| Injection-site pain | 200 | 152 | 97 | 93 |
| Injection-site swelling | 121 | 68 | 52 | 65 |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Experiencing a Solicited Injection Site Reaction (ISR) Related to the NeisVac-C® (MCC) Vaccination

| End point title | Number of Participants Experiencing a Solicited Injection Site Reaction (ISR) Related to the NeisVac-C® (MCC) Vaccination |
|---|---|

End point description:

The number of participants experiencing solicited ISRs related to the NeisVac-C® (MCC) vaccination was assessed. Solicited ISRs (erythema, pain and swelling) occurring at the NeisVac-C® (MCC) injection site were always considered related to the NeisVac-C® (MCC) vaccine. All AEs/ISRs were recorded on the VRC by the participant's parent(s)/legal representative. Data are presented for the number of participants experiencing solicited ISRs up to Day 5 after each NeisVac-C® vaccination and after any NeisVac-C® vaccination. Analysis Population: all participants receiving ≥1 dose of NeisVac-C® vaccination with corresponding safety follow-up data after each vaccination (for V1 and V2 arms) and after any vaccination (for V1; V2 arm) with NeisVac-C®.

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

End point timeframe:

Up to Day 5 following each vaccination

| **End point values** | PR5I (V1) | Pediacel® (V2) | PR5I (V1); Pediacel® (V2) | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 385 | 385 | 385 | |
| Units: Participants | | | | |
| Injection-site erythema | 41 | 59 | 85 | |
| Injection-site pain | 113 | 89 | 151 | |

| | | | | |
|---|---|---|---|---|
| Injection-site swelling | 34 | 42 | 66 | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Experiencing an Unsolicited Injection Site Reaction (ISR) Related to the PR5I/Pediacel® Vaccination

| End point title | Number of Participants Experiencing an Unsolicited Injection Site Reaction (ISR) Related to the PR5I/Pediacel® Vaccination |
|---|---|

End point description:

The number of participants experiencing unsolicited ISRs related to the PRI5 or Pediacel® vaccination was assessed. Unsolicited ISRs occurring at the PR5I or Pediacel® injection site were always considered related to the PR5I or Pediacel® vaccine, respectively. All AEs/ISRs were recorded on the VRC by the participant's parent(s)/legal representative. Data are presented for the number of participants experiencing unsolicited ISRs up to Day 15 after each vaccination and after any vaccination. Analysis Population: all participants receiving ≥1 dose of PR5I/Pediacel® vaccination with corresponding safety follow-up data after each vaccination (for V1, V2, and V3 arms) and after any vaccination (for overall V1; V2; V3 arm) with PR5I/Pediacel®.

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

End point timeframe:

Up to Day 15 following each vaccination

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 385 | 385 | 385 | 384 |
| Units: Participants | | | | |
| Injection-site bruising | 1 | 1 | 0 | 0 |
| Injection-site discomfort | 1 | 0 | 1 | 0 |
| Injection-site haematoma | 3 | 1 | 1 | 1 |
| Injection-site haemorrhage | 1 | 0 | 1 | 0 |
| Injection-site induration | 16 | 5 | 4 | 8 |
| Injection-site warmth | 1 | 1 | 0 | 1 |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Experiencing an Unsolicited Injection Site Reaction (ISR) Related to the NeisVac-C® (MCC) Vaccination

| End point title | Number of Participants Experiencing an Unsolicited Injection Site Reaction (ISR) Related to the NeisVac-C® (MCC) Vaccination |
|---|---|

End point description:

The number of participants experiencing unsolicited ISRs related to the NeisVac-C® (MCC) vaccination was assessed. Unsolicited ISRs occurring at the NeisVac-C® (MCC) injection site were always considered related to the NeisVac-C® (MCC) vaccine. All AEs/ISRs were recorded on the VRC by the participant's parent(s)/legal representative. Data are presented for the number of participants experiencing unsolicited ISRs up to Day 15 after each NeisVac-C® vaccination and after any NeisVac-C® vaccination. Analysis Population: all participants receiving ≥1 dose of NeisVac-C® vaccination with corresponding safety follow-up data after each vaccination (for V1 and V2 arms) and after any vaccination (for V1; V2 arm) with NeisVac-C®.

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

End point timeframe:

Up to Day 15 following each vaccination

| **End point values** | PR5I (V1) | Pediacel® (V2) | PR5I (V1); Pediacel® (V2) | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 385 | 385 | 385 | |
| Units: Participants | | | | |
| Injection-site discolouration | 1 | 0 | 1 | |
| Injection-site haematoma | 0 | 2 | 2 | |
| Injection-site induration | 2 | 2 | 4 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of Participants Experiencing a Solicited Systemic Adverse Event (AE)

| End point title | Number of Participants Experiencing a Solicited Systemic Adverse Event (AE) |
|---|---|

End point description:

The number of participants experiencing solicited systemic AEs (crying, decreased appetite, irritability, somnolence, pyrexia, and vomiting) was assessed. Each day from Day 1 to Day 5 following each vaccination, the participant's parent(s)/legal representative recorded all solicited AEs on the VRC. Data are presented for the number of participants experiencing solicited AEs up to Day 5 after each vaccination and after any vaccination. Analysis Population: all participants receiving ≥1 dose of any vaccination with corresponding safety follow-up data after each vaccination (for V1, V2, and V3 arms) and after any vaccination (for overall V1; V2; V3 arm).

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

End point timeframe:

Up to Day 5 following each vaccination

| End point values | PR5I (V1); Pediacel® (V2); PR5I (V3) | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 385 | 385 | 385 | 384 |
| Units: Participants | | | | |
| Crying | 255 | 188 | 131 | 102 |
| Decreased appetite | 195 | 141 | 88 | 76 |
| Irritability | 268 | 196 | 154 | 119 |
| Pyrexia | 52 | 19 | 24 | 18 |
| Somnolence | 229 | 184 | 126 | 84 |
| Vomiting | 88 | 56 | 35 | 27 |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Experiencing an Unsolicited Systemic Adverse Event (AE)

| End point title | Number of Participants Experiencing an Unsolicited Systemic Adverse Event (AE) |
|---|---|

End point description:

The number of participants experiencing unsolicited systemic AEs was assessed. Data are presented for the number of participants experiencing unsolicited AEs up to Day 15 after each vaccination and after any vaccination. Analysis Population: all participants receiving ≥1 dose of any vaccination with corresponding safety follow-up data after each vaccination (for V1, V2, and V3 arms) and after any vaccination (for overall V1; V2; V3 arm).

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

End point timeframe:

Up to Day 15 following each vaccination

| End point values | PR5I (V1); Pediacel® (V2); PR5I (V3) | PR5I (V1) | Pediacel® (V2) | PR5I (V3) |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 385 | 385 | 385 | 384 |
| Units: Participants | 163 | 58 | 53 | 89 |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of Participants Experiencing a Serious Adverse Event (SAE)

| End point title | Number of Participants Experiencing a Serious Adverse Event (SAE) |
|---|---|

End point description:

An SAE is an adverse event (AE) that: results in death; is life threatening; results in persistent or significant disability or incapacity; results in or prolongs a hospitalization; is a congenital anomaly or birth defect; is a cancer; or may jeopardize the participant, potentially require medical or surgical intervention. Analysis Population: all participants receiving ≥1 dose of study vaccination.

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

End point timeframe:

Up to ~6 months (at any time during the study)

| **End point values** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 385 | | | |
| Units: Participants | 12 | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to ~6 months (Serious adverse events and deaths were collected for the duration of the study. Solicited ISRs / AEs were collected up to 5 days following each vaccination; unsolicited ISRs / AEs were collected up to 15 days following each vaccination.)

Adverse event reporting additional description:

Analysis population includes all participants receiving ≥1 dose of study vaccination.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | PR5I (V1); Pediacel® (V2); PR5I (V3) |

Reporting group description:

[Vaccination 1]: Single doses of PR5I (V419) + NeisVac-C® + Prevenar 13® by intramuscular (IM) injection + oral RotaTeq®, given at 2 months of age. [Vaccination 2]: Single doses of Pediacel® + NeisVac-C® + Prevenar 13® by IM injection + oral RotaTeq®, given at 4 months of age. [Vaccination 3]: Single dose of PR5I (V419) by IM injection + oral RotaTeq®, given at 6 months of age.

| **Serious adverse events** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 12 / 385 (3.12%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Head injury | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Overdose | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchospasm | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Choking | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 5 / 385 (1.30%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Sepsis | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 385 (0.26%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

Frequency threshold for reporting non-serious adverse events: 2 %

| **Non-serious adverse events** | PR5I (V1); Pediacel® (V2); PR5I (V3) | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 360 / 385 (93.51%) | | |
| Nervous system disorders | | | |
| Somnolence | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 229 / 385 (59.48%) | | |
| occurrences (all) | 414 | | |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 255 / 385 (66.23%) | | |
| occurrences (all) | 452 | | |
| Injection site erythema | | | |
| subjects affected / exposed | 152 / 385 (39.48%) | | |
| occurrences (all) | 316 | | |
| Injection site induration | | | |
| subjects affected / exposed | 19 / 385 (4.94%) | | |
| occurrences (all) | 21 | | |
| Injection site pain | | | |
| subjects affected / exposed | 208 / 385 (54.03%) | | |
| occurrences (all) | 544 | | |
| Injection site swelling | | | |
| subjects affected / exposed | 130 / 385 (33.77%) | | |
| occurrences (all) | 261 | | |
| Pyrexia | | | |
| subjects affected / exposed | 56 / 385 (14.55%) | | |
| occurrences (all) | 69 | | |
| Gastrointestinal disorders | | | |
| Constipation | | | |
| subjects affected / exposed | 11 / 385 (2.86%) | | |
| occurrences (all) | 12 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 15 / 385 (3.90%) | | |
| occurrences (all) | 17 | | |
| Vomiting | | | |
| subjects affected / exposed | 93 / 385 (24.16%) | | |
| occurrences (all) | 136 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 9 / 385 (2.34%) | | |
| occurrences (all) | 12 | | |
| Psychiatric disorders | | | |

| | | | |
|---|---|---|---|
| Irritability | | | |
| subjects affected / exposed | 268 / 385 (69.61%) | | |
| occurrences (all) | 499 | | |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 16 / 385 (4.16%) | | |
| occurrences (all) | 16 | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 11 / 385 (2.86%) | | |
| occurrences (all) | 11 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 21 / 385 (5.45%) | | |
| occurrences (all) | 23 | | |
| Respiratory tract infection | | | |
| subjects affected / exposed | 12 / 385 (3.12%) | | |
| occurrences (all) | 13 | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 8 / 385 (2.08%) | | |
| occurrences (all) | 9 | | |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 196 / 385 (50.91%) | | |
| occurrences (all) | 319 | | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported